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Science Policy Study—Hearings Volume 15

SCIENCE AND THE REGULATORY ENVIRONMENT

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182

HEARINGS

BEFORE THE

TASK FORCE ON SCIENCE POLICY

OF THE

COMMITTEE ON SCIENCE AND TECHNOLOGY HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

FEBRUARY 26; MARCH 5, 6, 1986

[No. 111]

Printed for the use of the
Committee on Science and Technology

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U.S. GOVERNMENT PRINTING OFFICE
60-243 O WASHINGTON : 1986

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* Ranking Republican Member.
** Serving on Committee on the Budget for 99th Congress.

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SCIENCE AND THE REGULATORY ENVIRONMENT

WEDNESDAY, FEBRUARY 26, 1986

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
TASK FORCE ON SCIENCE POLICY,
Washington, DC.

The task force met, pursuant to recess, at 8:30 a.m., in room 2325, Rayburn House Office Building, Hon. Don Fuqua (chairman of the subcommittee) presiding.

Mr. FUQUA. Today's meeting is a continuation of our Science Policy Task Force hearings which were initiated last year to review the role that the Federal Government plays in support of research.

At this meeting we want to broaden our understanding of the effects of regulations on science research, which will enable us to determine how the future Government-science relationship and that area should be developed.

Although certain aspects of the regulation of science, such as national security restraints on dissemination, has received special attention in recent years, our focus today will be on all aspects of regulation as it applies to science. We want to determine the common aspects of such regulatory activities, be they relevant to research on human subjects or to the effects of certain types of chemicals and biological research on the environment.

It is important for the United States to retain the benefits of scientific progress and at the same time protect public health, safety, and values. Therefore, we must develop the principles for maintaining this needed balance between freedom of research and protection of the public in all scientific fields.

The Office of Technology Assessment has recently completed, at our request, a report on "The Regulatory Environment for Science." This report will serve as a good focal point for this hearing.

Today we will hear from the OTA and next week we look forward to having several outstanding experts in this field comment on the OTA's report.

And our first speaker today will be Dr. Marcel La Follette, assistant professor of exposition and rhetoric at the Massachusetts Institute of Technology and formerly the OTA project director. She is accompanied by two people who were here last week, Dr. John Andelin and Ms. Nancy Naismith.

So, if you will proceed, Dr. La Follette.

[The biographical sketches of Dr. La Follette, Ms. Naismith, and Dr. Andelin follow:]

Dr. Marcel Chotkowski La Follette

Marcel Chotkowski La Follette is Assistant Professor of Exposition and Rhetoric at the Massachusetts Institute of Technology and editor of the journal, *Science, Technology and Human Values*, which is co-sponsored by Harvard University and MIT. She has served as a consultant to the National Science Foundation and the National Endowment for the Humanities. From September 1984 to August 1985 she was a Congressional Fellow at the Office of Technology Assessment where she directed the project, The Regulatory Environment for Science.

Dr. La Follette was born in Little Rock, Arkansas and completed her B.S. in physics in 1967 at Little Rock University. She holds an M.S. from Boston University (1968) and a Ph.D. from Indiana University (1979). From 1977 through 1981 she held academic appointments at Harvard University. She has been at MIT since 1979.

Her major publication include; two edited collections, *Quality in Science* (1982) and *Creationism, Science, and the Law: The Arkansas Case* (1983), and over 30 articles and editorials on topics in science policy and on the social impact of science and technology. Her research and teaching focus on regulatory issues, public perceptions of Science and Technology and the communication of Science.

Nancy Carson Naismith

Nancy Carson Naismith is Program Manager for work in Science, Education, and Transportation at the Congressional Office of Technology Assessment (OTA). OTA provides analysis of the positive and negative impacts of technology choices for Congress.

Ms. Naismith has worked in the Executive and Legislative branches of the Federal Government since 1962. Her early work includes managerial responsiblity in the areas of water quality, open space and neighborhood development, historic preservation, and recreation planning. Since joining OTA in 1977, Ms. Naismith has worked primarily in energy technology, with special emphasis in energy conservation and renewable technologies. She also served as the first Vice President of the Solar Bank.

She holds a degree in general studies from the University of Washington in Seattle, and a Master's degree in Public Administration from the John F. Kennedy School of Government at Harvard, where she was a Littauer Fellow.

Dr. John P. Andelin, Jr.

Dr. John P. Andelin, Jr., is Assistant Director of the Congressional Office of Technology Assessment (OTA) for the Science, Information, and Natural Resources Division. Before his appointment at OTA, Dr. Andelin was the staff director for the Subcommittee on Advanced Energy Technologies and Energy Conservation Research, Development, and Demonstration of the Committee on Science and Technology, U.S. House of Representatives. He also served as a science consultant to that Committee and as scientific advisor and administrative assistant to Congressman Mike McCormack (D-Wash.).

Dr. Andelin holds a Ph.D. in physics from the California Institute of Technology and a Master's degree in physics from Stanford University. He has been on the research staff at Harvard University, Oak Ridge National Laboratory, and the Ford Scientific Laboratory.

STATEMENT OF DR. MARCEL C. La FOLLETTE, ASSISTANT PROFESSOR OF EXPOSITION AND RHETORIC, MASSACHUSETTS INSTITUTE OF TECHNOLOGY AND EDITOR OF SCIENCE, TECHNOLOGY AND HUMAN VALUES, FORMERLY PROJECT DIRECTOR, THE REGULATORY ENVIRONMENT FOR SCIENCE, ACCOMPANIED BY DR. JOHN P. ANDELIN, JR., ASSISTANT DIRECTOR, SCIENCE, INFORMATION, AND NATURAL RESOURCES DIVISION, OFFICE OF TECHNOLOGY ASSESSMENT; AND MS. NANCY CARSON NAISMITH, PROGRAM MANGER, SCIENCE, EDUCATION, AND TRANSPORTATION, OFFICE OF TECHNOLOGY ASSESSMENT

Dr. La Follette. Mr. Chairman, I am pleased to appear before you today to present the findings of OTA's technical memorandum, "The Regulatory Environment for Science." In fall 1984, the Office of Technology Assessment was asked by the Task Force on Science Policy of the House Committee on Science and Technology to examine the emerging regulatory environment for the conduct of scientific research. The task force requested that the study be general in nature, and that it cover the sometimes conflicting interests of public values, concerns about the potential ili effects of scientific research and the need for scientific freedom.

In answering this request, OTA adopted a broad definition of regulation, for institutional standards, citizen participation, and peer pressure can just as effectively force action as can regulation in the form of Executive orders, laws or agency rulemaking. The value of this situation lies in its democratic and pluralistic nature. The danger, however, lies in the potential for uncoordinated and potentially conflicting regulatory actions which create a research environment where controls are widespread, synergistic, and cumulative.

The OTA report examined the many forms of control that are exerted on the scientist in the course of his or her research, both directly and indirectly. Mechanisms for direct governmental control include review commissions and ethics advisory boards, legislative review, moratoria, regulations on the use or possession of substances used in research, contract provisions, and dissemination and publication controls. Indirect controls are exerted through administrative requirements on institutions or organizations that accept Federal grants or contracts, protective legislation such as antidiscrimination statutes and privacy legislation, and environmental and public health regulations. None of these laws were deliberately intended to control research, but their implementation applies to the research setting, adding additional administrative chores to the laboratory schedule. The very multiplicity of mechanisms for restraint increases the possibility that such regulations will be implemented piecemeal, in isolation, and without coordination.

These controls affect every stage of the research process—what topics appear on the research agenda, the procedures and materials used to conduct the research, and to whom the research may be disseminated. Because science is so diverse, and is conducted in so many settings, the regulatory forces at work on the various stages of research are not uniform and do not apply with equal pressure.

In two case studies, OTA reviewed the regulatory environment for science in agricultural research and in research on acquired immunodeficiency syndrome, or AIDS. These case studies were used to illustrate the intensely political environment that surrounds some research, affecting the entire research process.

The agricultural research system is highly structured, involving both Federal and State agencies. For many years, a multiplicity of actors—consumers, producers, investors, in-house scientists, scientific societies, the regulatory agencies, the executive branch, and the Congress—have determined research priorities. Recently, two separate legal actions have introduced controversy into what has usually been a quiet region of the scientific community. These actions have had a dramatic influence on the research process in agriculture, attempting to prohibit research from progressing on certain topics or in a certain manner.

In the first action, attorneys filed suit on behalf of 17 farmworkers, charging the University of California with unlawfully spending public funds on mechanization research that displaced farmworkers. That suit is still in litigation. The second action is a suit filed to halt the deliberate release of genetically-engineered products into the environment, a technology of potential use to the agricultural industry as a means of increasing and improving crop production. A Federal appeals court has ruled that experiments involving the release of genetically-altered organisms into the environment can proceed, provided that their potential ecological effects have been properly evaluated. After 2 years of regulatory scrutiny, a biotechnology company was given approvel to conduct a deliberate release experiment in Monterey County CA. That experiment has now been delayed because the county board of supervisors held a public hearing in response to citizen opposition and indicated that it would use its zoning authority to place a moratorium on that experiment.

Mr. FUQUA. According to the news this morning, they did not honor that. They have already gone ahead and had some release.

Dr. LA FOLLETTE. I heard that. Yes.

Mr. FUQUA. I don't know the facts of that, but that was reported.

Dr. LA FOLLETTE. Yes.

Mr. FUQUA. Excuse me.

Dr. LA FOLLETTE. Well, as you point out, these two legal illustrations illustrate very well that even the most highly controlled of research fields may be disrupted by new regulatory forces.

In the case of research on AIDS, regulatory forces may have contributed to and impeded research into the cause and cure of the disease. The methodological traditions of science, which are manifested in an extensive grants application and approval process, and some significant liability and privacy issues may, in fact, now be colliding with the push by advocacy groups for acceleration of the research.

While it is true that scientists have always exercised restraints on their work, the introduction of Government-based, legally enforceable regulations is relatively new. When the Bush and Steelman reports outlined their visions for how the Federal Government should sponsor and finance a national structure for scientific research, there was little reason to believe that the resulting ar-

rangements could become the vehicles through which research might be regulated according to prevailing social or political attitudes. There may be several reasons for this change. As the funding patterns for R&D shifted after World War II—with the Federal Government assuming an ever-larger share of U.S. research funding—the justification for Government intervention in all aspects of the research process also increased. Because it was regarded as a public good, science became susceptible to direction and control by the Federal Government.

Because much of Government sponsored research occurs in the universities and the regulations are often tied to grants, most of the discussion of and complaints about overregulation have been concentrated on universities—I should add, in universities. From a comparison of controls exerted on research in different settings, however, OTA concluded that regulatory effects—especially in the research process—are not confined to universities alone. Many of the mechanisms apply with equal force to research in industry and private laboratories.

In addition, OTA found that broad interpretation of some regulations has led to the application of regulations intended for industry through the university setting and vice versa. This creates an environment where, from the researcher's view, the complexity of compliance may make the original intent of the law appear unreasonable. An example cited in our profile of a representative university chemistry laboratory provides such an illustration. Much of the department's research is conducted on a very small scale, utilizing small quantities—often less than a gram—of chemicals in a particular step. Yet the transportation, storage and use of these chemicals is highly regulated under the Toxic Substances Control Act. The same standards of compliance required of industry—which may use massive quantities of the toxic substance in production processes—are also required of the university chemistry lab. Some observers propose that, in principle, the cost imposed on various economic or research activities by regulation should be in proportion to the potential environmental, health, or safety impact of these activities. One analyst observed that "universities are not quite the uniquely subtle and complex organisms they like to consider themselves, but they do possess a good many characteristics that make regulations suitable to a steel mill not always relevant or appropriate to a university."

An OTA survey of laboratory directors and research administrators revealed that most scientists do not question the need for certain types of control, but are upset by the multiplicity of the rules. Research institutions perceive that, because of the complexity of and effort required to assure compliance, both time and money are being taken from the actual research. This perception creates tension between scientist and administrator and between scientist and granting agency. Recently, the National Academy of Science's Government-University-Industry Research Roundtable has initiated important discussions about reducing some of this "bureaucratic accretion" in the sponsored research system.

In addition to increasing regulation of the conduct of research, scientists in the 1980's face increasing control of the dissemination and communication of research results. Concerns about national se-

curity and export controls have changed the Federal posture on communication of basic science. Although the use of such controls is not new, the comprehensiveness of the new constraints is a recent development.

The discovery, during World War II and in the subsequent U.S. nuclear program, that basic research could have considerable value for maintaining the Nation's military security led to increased funding of research by the Department of Defense and a resulting increase in the proportion of classified research. Traditionally, Federal policy has been supportive of open communication, free exchange of information and wide publication in scientific research. From time to time, the Department of Defense advanced arguments for imposing official secrecy on research or restrictions on the dissemination of certain types of research and the scientific community has, by and large, cooperated. Because of this history of open communication in general, with defense-related restrictions imposed on a case-by-case basis, efforts to implement broad restrictions on the communication of basic science—as embodied in the Export Administration Regulations and International Traffic in Arms Regulations—have been met with criticism and occasional resistance from the scientific community.

In the decision to classify or control scientific information, the risks to national security must be weighed against the long-term value of free flow of information among scientists and against principles of scientific and academic freedom. Many critics of sweeping controls on communication argue that, in the long run, such restraints could harm the quality of the scientific work force, the traditional climates for creativity, and the very progress in basic science that is necessary to technological development and international technological competitiveness. Clearly, this is an important regulatory issue for science in the 1980's.

OTA foresees other increasingly difficult issues arising regarding intellectual property, as well as types of classification, due to new information technologies. The information revolution creates new opportunities for transmitting information as well as opportunities for more open dissemination. Publication on electronic networks could have the effect of increasing the amount of scientific information if, because of the speed of publication on such networks, the Government feels compelled to act quickly to classify without adequate information to justify such classification. New technologies also give rise to questions about how much control an originator has over the research project's results or data—that is, its intellectual property.

OTA found an additional trend in the regulatory environment for science and that is, the increasingly active role of the public as participant in debates over the conduct of research. The uncovering of a number of examples of abuses of human subjects, growing fears that scientific research was creating technologies that posed high risks to human health, and the public identification of research as a Government-sponsored activity were catalysts for public action in the 1960's and 1970's.

The increased environmental regulation of industry—as well as other social legislation—had a number of unplanned effects on the scientific research system. The increased regulation of science may

indicate that science is simply included as a target of society's willingness to regulate all types of institutions, professions or activities. It may well be that such regulation reflects the American public's willingness to restrict research when the risk is perceived to be too great, despite public opinion data which show that there is widespread support for science as a cultural activity deserving Federal support.

OTA analyzed instances where citizen concern affected a research program, with crucial policy decisions occurring at the local level. Two of these cases involved precedent-setting interventions into scientific inquiry by the city of Cambridge, MA. The first case was Cambridge's two-phase regulation of recombinant DNA technology, enacted in response to concerns in the academic community about the potential dangers of recombinant DNA research, the second case was the city's effort to proscribe the handling and testing of certain chemical warfare agents by a consulting firm that was under contract with the Department of Defense. Another recent case discussed briefly in the OTA report involved a controversy about siting of a telecommunications research complex by Bell Communications Research, Inc., in Morris Township, NJ. Citizens in Morris Township were concerned there about the storage, use, and disposal of highly toxic and flammable gases at the proposed site. In all three cases, it is possible that perceived risk to the community was the motivation for restraining action.

Although the evidence is limited, these and other cases hint at the beginning of a jurisdictional shift in the regulatory arena for science—especially from the Federal to the State and local. This change may be a reaction to either real or perceived laxity in Federal regulations for health and safety protection, or it may relate to broader issues of the exertion of local control over land use and community activity. In some cases, it relates to the larger agenda of national political groups, for example, protest linked to nationwide efforts to stop all nuclear power, abortions, or the use of animals. In some cases, as in the Morris Township Bellcore case, community concern may be totally unrelated to the goals of the research, but instead, may be derived from concerns about the potential hazards posed by the use of certain chemicals in the process of research. Nevertheless, citizen action has been shown to be powerful enough to delay or halt completely certain types of research or research using specific chemicals or techniques in both industry and university settings.

This apparent jurisdictional shift raises a number of questions about the effects on research of inconsistencies or variations in the strictness of Federal and local regulations. It has been suggested that, should this trend continue, States without the resources for developing comprehensive regulations, or for assuring compliance, might become dumping grounds for research no other States want.

OTA asks whether there is a need for a new framework by which Congress can deal with these jurisdictional issues. Or, are they best resolved at the State and local level? The emergence of a number of cases in which research facilities have been the subject of local protests indicates that research no longer wears a mantle of unquestionable civic respectability. Instead, it is subject to the same

political influences and attitudes at the local level as are our other institutions.

OTA found numerous other, more generalized, jurisdictional issues. Indeed, one of the principal unresolved issues in the control of scientific research is that of who should be involved in the regulatory process. What is the appropriate role for the individual scientist, for a professional science or engineering society, or for the public? What is the role of the scientists in assuring that their research is safe? OTA found that the burden of proof for control of research appears to be changing.

How much should research be controlled by legal regulation, how much by institutional rules, and how much left to informal practice, or to codes or guidelines of professional societies? The topic of the regulatory environment for research involves discussion of some of the most basic questions of American political philosophy—public control versus self-rule, Federal versus local jurisdiction, the feasibility of regulation, and the importance of consent by the regulated, Government regulation versus individual liberty, and how to balance the conflicting rights and values of different social institutions. The events and the debate will continue. Congress can expect to confront these issues again and again.

Thank you.

[The prepared statement of Dr. La Follette follows:]

STATEMENT OF DR. MARCEL C. LA FOLLETTE
Project Director*
The Regulatory Environment for Science
Accompanied by Nancy C. Naismith
Science, Education, and Transportation Program
Office of Technology Assessment

Before the House Committee on
Science and Technology
Science Policy Task Force

THE REGULATORY ENVIRONMENT FOR SCIENCE

February 26, 1986

* currently Assistant Professor of Exposition and Rhetoric
Massachusetts Institute of Technology

TESTIMONY OF DR. MARCEL C. LA FOLLETTE

TO THE

HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

SCIENCE POLICY TASK FORCE

February 26, 1986

Mr. Chairman, I am pleased to appear before you today to present the findings of OTA's technical memorandum, The Regulatory Environment for Science. In Fall 1984 the Office of Technology Assessment was asked by the Task Force on Science Policy of the House Committee on Science and Technology to examine the emerging regulatory environment for the conduct of scientific research. The Task Force requested that the study be general in nature, and cover the sometimes conflicting interests of public values and concerns about the potential ill effects of scientific research and the need for scientific freedom.

In answering this request, OTA adopted a broad definition of regulation, for institutional standards, citizen participation, and peer pressure can just as effectively force action as can regulation in the form of Executive Orders, laws, or agency rulemaking. The value of this "cobweb" of control lies in its democratic and pluralistic

nature. The danger of this system, however lies in the potential for uncoordinated and potentially conflicting mechanisms for control, which create a research environment where controls are widespread, synergistic, and cumulative.

The OTA report examined the many forms of control that are exerted on the scientist in the course of his or her research, both directly and indirectly. Mechanisms for direct governmental control include review commissions and ethics advisory boards, legislative review, moratoria, regulations on the use or possession of substances used in research, contract provisions, and dissemination and publication controls. Indirect controls are exerted through administrative requirements on universities that accept federal grants or contracts, protective legislation such as anti-discrimination statutes and privacy legislation, and environmental and public health regulations. None of these laws were deliberately intended to control research, but their implementation applies to the research setting, adding additional administrative chores to the laboratory schedule. The very multiplicity of mechanisms for restraint increases the possibility that such regulations will be implemented piecemeal, in isolation, and without coordination.

These controls affect every stage of the research process — what topics appear on the research agenda, the procedures and materials used to conduct the research, and to whom the research results may be disseminated. Because science is so diverse, and is conducted in so many settings, the regulatory forces at work on the various stages of research are not uniform and do not apply with equal pressure. In two case studies, OTA reviewed the regulatory environment for science in agricultural research and in research on acquired immunodeficiency syndrome (AIDS). These case studies illustrate the intensely political environment that surrounds some research, affecting the entire research process.

The agricultural research system is highly structured, involving both Federal and State agencies. For many years a multiplicity of actors — consumers, producers, investors, in-house scientists, scientific societies, the regulatory agencies, the executive

branch, and Congress — have determined research priorities. Recently, two separate legal actions have introduced controversy into what has usually been a quiet region of the scientific community. These actions have had a dramatic influence on the research process in agriculture, attempting to prohibit research from progressing on certain topics or in a certain manner.

In the first action, attorneys filed suit on behalf of 17 farm workers, charging the University of California with unlawfully spending public funds on mechanization research that displaced farm workers. That suit is still in litigation. The second action is a suit filed to halt the deliberate release of genetically engineered products into the environment, a technology of potential use to the agricultural industry as a means of increasing and improving crop production. A Federal appeals court has ruled that experiments involving the release of genetically altered organisms into the environment can proceed, provided that their potential ecological effects have been properly evaluated. After two years of regulatory scrutiny, a biotechnology company was given approval to conduct a deliberate release experiment in Monterey County, California, but was stopped in its tracks when the county board of supervisors held a public hearing in response to citizen opposition and indicated that it would use its zoning authority to place a moratorium on the experiment.

These two legal actions demonstrate that even the most highly controlled of research fields may be disrupted by new regulatory forces.

In the case of research on AIDS, regulatory forces have both contributed to and impeded research into the cause and cure of the disease. The methodological traditions of science — manifested in an extensive grants application and approval process — and some significant liability and privacy issues may be colliding with the push by advocacy groups for acceleration of the research.

While it is true that scientists have always exercised restraints on their work, the introduction of government-based, legally enforceable regulations is relatively new. When the Bush and Steelman reports outlined their visions for how the Federal Government should sponsor and finance a national structure for scientific research, there was little reason to believe that the resulting arrangements could become the vehicles through which research might be regulated according to prevailing social or political attitudes. There may be several reasons for this change. As the funding patterns for R&D shifted after World War II — with the Federal government assuming an ever larger share of all U.S. research funding — the justification for government intervention in all aspects of the research process also increased. Because it was now regarded as a "public good", science became susceptible to direction and control by the Federal government.

Most of the discussion of and complaints about overregulation have been concentrated on universities. From a comparison of controls exerted on research in different settings, however, OTA concluded that regulatory effects, especially in the research process, are not confined to universities. Many of the mechanisms apply with equal force to research in industry and private laboratories.

In addition, OTA found that broad interpretation of some regulations has lead to the application of regulations intended for industry to the university setting and vice versa. This creates an environment where, from the researcher's view, the complexity of compliance may make the original intent of the law appear unreasonable. An example cited in our profile of a representative university chemistry laboratory provides an illustration. Much of the department's research is conducted on a very small scale, utilizing small quantities (often less than a gram) of chemicals in any particular step. Yet, the transportation, storage, and use of these chemicals is highly regulated under the Toxic Substances Control Act. The same standards of compliance required of industry, which may use massive quantities of the toxic substance in production processes, are also required of the university chemistry lab. Some observers propose that, in principle, the

cost imposed on various economic or research activities by regulation should be in proportion to the potential environmental, health, or safety impact of these activities. One analyst observed that "universities are not quite the uniquely subtle and complex organisms they like to consider themselves, but they do possess a good many characteristics that make regulations suitable to a steel mill not always relevant or appropriate to a university."

An OTA survey of laboratory directors and research administrators revealed that most scientists don't question the need for certain types of control, but are upset by the multiplicity of the rules. Research institutions perceive that because of the complexity of and time required to assure compliance, both time and money are being taken from the actual research. This perception creates tension between scientist and administrator, and between scientist and granting agency. Recently, the National Academy of Science's Government-University-Industry Research Roundtable has initiated important discussions about reducing "bureaucratic accretion" in the sponsored research system.

In addition to increasing regulation of the conduct of research, scientists in the 1980s face increasing control of the dissemination and communication of research results. Concerns about national security and export controls have changed the Federal posture on communication of basic science. While the use of such controls is not new, the comprehensiveness of the new constraints is a recent development.

The discovery during World War II — and in the subsequent U.S. nuclear program — that basic research could have considerable value for maintaining the Nation's military security led to increased funding of research by the Department of Defense and a resulting increased in the proportion of classified research. Traditionally, federal policy has been largely supportive of open communication, free exchange of information, and

wide publication in scientific research. From time to time, the Department of Defense advanced arguments for imposing official secrecy on research or restrictions on the dissemination of certain types of research and the scientific community has by and large cooperated. Because of this history of open communication in general with defense-related restrictions imposed on a case-by-case basis, efforts to implement broad restrictions on the communication of basic science — as embodied in the Export Administration Regulations and International Traffic in Arms Regulations — have been met with criticism and occasional resistance from the scientific community.

In the decision to classify or control scientific information, the risks to national security must be weighed against the long-term value of free flow of information among scientists and against principles of scientific and academic freedom. Critics of sweeping controls on communication argue that, in the long run, such restraints could harm the quality of the scientific work force, the traditional climates for creativity, and the progress in basic science that is necessary to technological development. Clearly, this is an important regulatory issue for science in the 1980s.

OTA foresees increasingly difficult issues arising regarding intellectual property, as well as various types of classification, due to new information technologies. The information revolution creates new opportunities for transmitting information as well as opportunities for more open dissemination. Publication on electronic networks could have the effect of increasing the amount of classification of scientific information if, because of the speed of publication on such networks, the Government feels compelled to act quickly to classify without adequate information to justify such classification. New technologies also give rise to questions about how much control an originator has over the research project's results or data — its intellectual property.

OTA found an additional trend in the regulatory environment for science — the increasingly active role of the public as participant in debates over the conduct of research. The uncovering of a number of examples of abuses of human subjects, growing fears that scientific research was creating technologies that posed high risks to human health, and the public identification of research as a government-sponsored activity were catalysts for public action in the 1960s and 1970s. The increased environmental regulation of industry — as well as other social legislation — had a number of unplanned effects on the scientific research system. The increased regulation of science may indicate that science is simply included as a target of society's increasing willingness to regulate all types of institutions, professions, or activities. In fact, public opinion data show that such regulation may reflect the American public's willingness to restrict research when the risk is perceived to be too great, despite the concurrent existence of widespread public support for science as a cultural activity deserving Federal support.

OTA analyzed instances where citizen concern affected a research program, with crucial policy decisions occurring at the local level. Two of these cases involved precedent-setting interventions into scientific inquiry by the city of Cambridge, Massachusetts. The first case was Cambridge's two-phase regulation of recombinant DNA technology, enacted in response to concerns in the academic community about the potential dangers of recombinant DNA research; the second case was the city's effort to proscribe the handling and testing of certain chemical warfare agents by a consulting firm under contract with the Department of Defense. Another case involved a controversy about siting of a telecommunications research complex by Bell Communications Research, Inc. in Morris Township, New Jersey. Citizens in Morris Township were concerned about the storage , use, and disposal of highly toxic and flammable gases at the proposed site. In all three cases, perceived risk to the community was the motivation for restraining action.

Although the evidence is limited, these and other cases hint at the beginning of a jurisdictional shift in the regulatory arena for science, especially from the Federal to the State and local. This change may be a reaction to either real or perceived laxity in Federal regulations for health and safety protection, or it may relate to broader issues of the exertion of local control over land use and community activity. In some cases, it relates to the larger agenda of national political groups, for example, protest linked to nationwide efforts to stop all nuclear power, abortions, or the use of animals. In some cases, as in the Morris Township Bellcore case, community concern may be totally unrelated to the goals of the research, but instead, may be derived from concerns about the potential hazards posed by the use of certain chemicals in the process of the research. Nevertheless, citizen action has been shown to be powerful enough to delay or completely halt certain types of research or research using specific chemical or techniques in both industrial and university settings.

This apparent jurisdictional shift raises a number of questions about the effects on research of inconsistencies or variations in the strictness of Federal and local regulations. States without the resources for developing comprehensive regulations (or for assuring compliance) might become dumping grounds for research no other States want.

OTA asks whether there is a need for a new framework by which Congress can deal with these jurisdictional issues, or are they best resolved at the state and local level? Clearly, the emergence of a number of cases in which research facilities have been the subject of local protests indicates that research no longer wears a mantle of unquestionable civic respectability. Instead, it is subject to the same political influences and attitudes at the local level as are other institutions.

OTA found numerous other, more generalized jurisdictional issues. Indeed, one of

the principal unresolved issues in the control of scientific research is that of who should be involved in the regulatory process. What is the appropriate role for the individual scientist, for a professional science or engineering society, or for the public? What is the role of the scientists in assuring that their research is safe? OTA found that the burden of proof for control of research appears to be changing.

How much should research be controlled by legal regulation, how much by institutional rules, and how much left to informal practice or to codes or guidelines of professional societies? The topic of the regulatory environment for research thus involves discussion of some of the most basic questions of American political philosophy — public control v. self-rule, Federal v. local jurisdiction, the feasibility of regulation and the importance of consent by the regulated, government regulation v. individual liberty, and how to balance the conflicting rights and values of different social institutions. The events and the debate will continue. Congress can expect to confront these issues again and again.

DISCUSSION

Mr. FUQUA. Thank you very much for a very excellent statement.

I guess you summed it up in the last paragraph. What is the trade-off between self-rule—which, in some cases, we have relied on the scientific community to do—versus when you get into public or local jurisdiction or some type of Federal regulation? Maybe we tend to overregulate and, in that case, it is not flexible encugh to respond to changing circumstances that may develop along the way. Has the scientific community, in your opinion, done a good job over the years—in self-regulation?

Dr. LA FOLLETTE. In my opinion, I think, by and large, it has in certain cases. I think that where I would propose some change would be in the willingness of the scientific community to enter into more open and frequent conversations, if you will, with the members of the affected public—or publics, in many cases.

Mr. FUQUA. In other words, don't take everything we say at face value? You have a right to question, or we have a right to explain why we think these things should be done in a certain way?

Dr. LA FOLLETTE. Yes. That the public or the affected publics or people who represent the wide or the general public have a right to enter into these discussions, even if they do not possess the technical knowledge that the scientific community has about the particular issue.

Sometimes a measure of patience, extra patience, may be required on the part of the scientific community to explain, and to educate the public in those technical issues—or to realize that the public may be wishing—may be expressing its desires for regulation on the basis of fears that have nothing to do with the technical issues that are of concern.

Mr. FUQUA. Yes.

Dr. LA FOLLETTE. That we may well, as individuals, have a right to say: "We do not want to run that risk, even if you assure us that the risk is very small." And that those desires—and wishes, if you will—be respected by the scientific community.

Mr. FUQUA. The OTA study indicated that now there is a higher percentage of private-funded research from industry that has evolved in the last 10 or 15 years, I guess. Is there any figure for, or data on the impact of regulatory costs on universities or for industry?

Dr. LA FOLLETTE. To the best of my knowledge, that information has not been compiled—unless my colleagues on the right and left have new information.

It was, let us say, intellectually frustrating in, of course, the project to find that we could not find such data. It is clear to me, as someone who has looked at the topic, that the collection of such data would be of use in both our deliberations as students of the subject but, perhaps, also be of use to the Congress and to the political sphere in making some decisions.

I know that, at the university level, many universities have compiled information about, let us say, the cost to the university of running a human subjects regulation committee—but, to the best of my knowledge, those statistics are compiled at the institutional

level. No one has collected them and there would be no common base for comparison of those statistics.

Mr. FUQUA. I think, in the report, it was noted that there was a 1979 study that showed that one year that an IRB was in session 41 times and reviewed 278 proposals, involving some 80,000 prospective research subjects, and it cost the university about $130 a proposal, for each proposal for that year. Has there been anything to suggest that this administrative cost is burdensome? Or have there been some added mechanisms suggested? Or should there be some counterparts required for institutions not receiving those kind of funds?

Dr. LA FOLLETTE. Here I must make clear I am speaking privately, not for OTA—and also, not for MIT.

Mr. FUQUA. We will accept that.

Dr. LA FOLLETTE. All right. I would say that, were you to ask the university administrators, that they would say such costs are burdensome—in a day when their budgets are under increasing pressure from a lot of different things. But I would also say that those same universities would not question the need for such regulation. But I think, increasingly, as we begin to look at the costs of those individual regulations on the universities, we may want to ask whether there is some way to share those burdens.

Mr. FUQUA. Well, would the costs get to the point that it would influence the type of research that an institution may wish to perform?

Dr. LA FOLLETTE. I think you might well suspect that that could happen. Indeed, that in some cases, the burden of having to comply with those regulations might create an atmosphere in which certain kinds of research would be discouraged.

Certainly, we know that if a university does not have the equipment—the large-scale equipment, computing equipment or whatever—to do certain kinds of research, then researchers will not be applying for grants in those areas.

Mr. FUQUA. Well, that is equipment.

Dr. LA FOLLETTE. Right. Yes, but——

Mr. FUQUA. That is a different subject. But if you are subjected to certain regulatory procedures that are burdensome, cost you $130 or maybe—and that is an average.

Dr. LA FOLLETTE. Yes.

Mr. FUQUA. Some are, I am sure, higher. Some are lower. But I am wondering what influence that would have and if there are any studies to that effect of that influence, of schools that have said, "Hey, we are not going to deal in animal research because it is too expensive?"

Or, "We are not going to deal in recombinant DNA because we do not want to keep up with all the records."

Dr. LA FOLLETTE. It is quite possible——

Mr. FUQUA. Or some other type.

Dr. LA FOLLETTE. Right.

Mr. FUQUA. That is just two illustrations.

Dr. LA FOLLETTE. Right. It is quite possible that that has happened. We have no data or information on that.

We do know, in our case studies, that the comparative case studies that were described in the OTA report, that the industrial re-

search group that was interviewed stated that they had not gone into a certain type of research because of the cost of maintaining a P-3 laboratory, if I remember correctly.

Mr. RITTER. Will the gentleman yield?

Mr. FUQUA. Yes. Sure.

Mr. RITTER. It has been my experience, in talking with venture capitalists, that this has happened and that venture capital—looking at innovative possibilities—is avoiding, to some extent, highly-regulated industries or highly-regulated situations. And I think you could safely say that chemicals and the involvement of potentially hazardous toxic chemicals is one of these areas where venture capital shies away from because they just see such an overriding cost of conforming with regulations that——

Mr. FUQUA. Yes. I was not really referring to doing business, though, Mr. Ritter, with regard to research.

Mr. RITTER. Yes, I understand. I have a feeling that the motivations are not so different between what is happening in the innovative side of business and, really, what is precursor to that business innovation—and that is, the basic science development in the universities.

I thank the gentleman for yielding.

Dr. LA FOLLETTE. Mr. Chairman, what is most likely is that such decisions are being made at the level of the individual investigator and so it would be very difficult to have any data or information on that at the institutional level; but that, certainly, researchers in the social sciences, for example, who may often find themselves subjected to some of the human subjects regulations if they construct their research design in a certain way, may well shape the research design so that they are not subject to such regulations. Or may decide to not go into a certain area.

But one can guess that that is happening.

Mr. FUQUA. Yes.

Dr. LA FOLLETTE. But whether it is happening at a broadscale institutional level, we do not know.

Mr. FUQUA. Well, in this 1985 survey of the laboratory directors and research administrators, they indicated that the administrative requirement of procurement in management was a major regulatory force of their institutions. And it increased substantially, which the funds required, which translates into doing less time and money spent on research. I think that was a conclusion. What are some of the short-term and long-term remedies for that? Because we are paying good money for research, we want to get the maximum amount of research and not have it all gobbled up in administrative or other bureaucratic costs associated with it.

Dr. LA FOLLETTE. I think that the National Academy may have made one step toward that in bringing together the administrators and the granting agencies in discussing what could be done about those types of regulations—which are indirect regulations on research.

It may well be that it would be useful to do the same thing for the—strictly on the question of administrative costs and administration on human subjects regulations and on animals—that probably may well be the easiest thing to do in the short term.

I am not sure if my colleagues have any other suggestions for that one.

And I might add, one of the difficulties is that the university sees itself subjected to not just one set of regulations but to a number of different regulations and it is not one individual burden, but it is the burden as a whole.

And it would be useful if we could compile information on the general administrative costs to particular universities.

Mr. RITTER. Would the chairman yield on that point as well?

Mr. FUQUA. Sure.

Mr. RITTER. We mentioned here in the question, administrators and lab directors. It is also faculty members. It is also individual scientists. And I think the chairman has hit on an extremely important point.

Faculty members, because of the variety of regulations dealing with some of the areas you are covering—and I assume the report is covering some of the more just administrative and bureaucratic paperwork that is involved—and the application process, the proposal process—some of our best faculty members are spending inordinate amounts of time seeking funding with agency after agency or keeping up their funding base. And, as the paperwork demands have increased, and as the regulatory demands have increased, this percentage is increasing and I think it has reached a point where we may be paying Nobel prizewinners or semi-Nobel prizewinners to be laboratory administrators and funding seekers. Do you have any comment on that? Has the study generated information on that?

Dr. LA FOLLETTE. I think the study—OTA has a very extensive review process—and I think we have found that those people who were faculty members in universities agreed with that interpretation. Again, there is no real—there is no hard data on what that particular administrative burden means to each individual researcher—but I would be hard-pressed to find a researcher at any university who would not second your comment.

Mr. RITTER. And if it has mushroomed, and if indirect costs mushroom in direct proportion, and university administrative personnel mushroom in direct proportion, then the question becomes, what do we do about it? How do we stem this tide? And, perhaps, bring back a little more decentralization or some more flexibility to the system.

Dr. LA FOLLETTE. One of our concerns in the discussions with the advisory committee for the OTA project was that this atmosphere of increasing burdens on the—just the administration of research, that burden on the individual researcher, might have an adverse effect on the young investigator who was not around—if you will—at the time we were having these discussions on human subjects regulations and that they might sometimes lose the thread of the justification for these regulations and see only the burden.

So there was some concern that, both, we need to do some education within the scientific community on the justifications for regulation but that, also, there was reason for concern if that burden tended to result, perhaps, in laxity at the individual level—certainly to resistance.

Mr. RITTER. I thank the chairman for yielding.

Mr. FUQUA. Of course, different schools have different ways that they perform their accounting procedures for overhead costs or indirect costs. That issue has been around for awhile, too. But we are really talking about not—the cost of overhead of doing business—but, really, the regulatory side of it, not just for cleaning up the lab and turning the lights on and the normal things associated with it.

An area that has been of great concern to us over the years has been the regulation on the export of technical information, and that has prohibited certain foreign nationals from attending open scientific meetings or society professional meetings, or required researchers to withdraw unclassified technical papers scheduled for presentation at professional meetings because certain foreign nationals may be present. Can you cite some specific examples? And is this very widespread? And what impact will it have on the collaboration between scientists of different countries with this potential hanging over their heads?

Dr. LA FOLLETTE. Well, we do have documentation of specific examples, as you know, where papers have been withdrawn. The scientific societies have, in some cases, cooperated with the Department of Defense and closed meetings at their request.

The American Association for the Advancement of Science has recently completed a survey, I know, of many major scientific societies in science and engineering and the committee may well, I hope, receive the results of that survey, too. But I have heard that that survey says that many of those societies do not have rules in place for determining what they would do, should such a request be made by the Department of Defense. Most of the societies are now beginning to consider that question, so it is a question of considerable concern at the scientific level. At the individual investigator level, it tends to concern those who have been affected and to be of some concern to others who see that as a potential threat to open communication in general in the scientific community.

My concern—and the concerns of many of my colleagues—would be that an atmosphere in which some communications were inhibited would have a long-term adverse effect on the quality of scientific research in the future since, as we know, our research tends to proceed by collegial interaction and to depend upon that for as long as science has been going on.

Mr. FUQUA. Also, the report makes reference to the loosening of some of the patent laws and the rationale is that it serves as a kind of impediment to use new experimental technology for the flow of information. But, on the other hand, if we loosen patent laws, won't we also diminish the enthusiasm for somebody to do innovative work looking for that ultimate patent that may be the—you know, solve a lot of solutions or make that person a lot of money or solve a lot of human misery—or the good things that could come from patents? Do you think that point should be made when we talk about patents?

Dr. LA FOLLETTE. I would agree with what you said. I am not an expert on patent law.

Mr. FUQUA. Neither am I. But we have dealt with it a lot. A lot of us nonexperts have been interested in dealing in this subject for some time.

Dr. LA FOLLETTE. My impression would be that that is one of the risks that we run, in all of the changes in the regulation of science; that, in making changes, we need to be sensitive to the way in which science has been structured so that we do not damage a system that we do know has been working very well.

Mr. FUQUA. Well, there was a philosophy prevailing for many years in the Congress saying that, if even 1 cent of Federal funds had been spent, then results must be shared with the Federal Government. And we found that that was an impediment to getting the patents commercialized and our idea was that—and the philosophy that was later adopted in the Congress and the most recent patent law changes which originated in this committee—was that that was counterproductive, that we needed to get the patents commercialized and to provide the person with protection, but to have an incentive so that there could be financial rewards at the end. And I think, when we talk about loosening patents, that are we then defeating the purpose of having patent laws in the first place.

John, maybe you wish to speak to that?

Dr. ANDELIN. Mr. Chairman, yes, if I might.

Mr. FUQUA. I think you might have been around here when we were first talking about changing the patent laws.

Dr. ANDELIN. I think what has been observed in recent years is that many of the more innovative industries—by all means, not all of them, but many of them—are less dependent on patents because of the rate at which the industry and the technology is changing. And so they depend a lot on proprietary information trade secrets as well. The other element of patents that has become more difficult over the last few decades is the very high cost of defending a patent, so that there is conflicting information.

Mr. FUQUA. Yes.

Dr. ANDELIN. It is clear that the venture capital industry is interested in patent protection. At the same time, the industries that one might expect to use patents extensively are depending more on trade secrets than they used to, so there is an area that warrants, I think, considerable further investigation by some future task force in some future year. Loosening of patents has some benefits as well as some problems.

Mr. FUQUA. Yes.

Mr. Ritter.

Mr. RITTER. Thank you, Mr. Chairman.

First of all, I would like to commend the chairman for holding these hearings and I would really like to commend OTA for this report. I think it is extremely important. It is timely. And I would hope that it receives wide recognition and review throughout the system.

I would also like to commend the staff for putting together what I feel is a very substantial body of questions and I understand that those that do not get asked—and I know the chairman has asked a few of them already and perhaps the rest of us will—but those that do not get asked, that the staff will submit these to the panel, because I think there is just a tremendous opening salvo fired here on this issue.

I would like to ask about the question of liability. We know that every day something is coming across our desks that indicates a

breakdown in insurability and liability and I would like to ask the panel, Where are we? How far are we at the university research level or the research laboratory and institute level from exposure to some of the insurability and liability questions which are starting to impact on the rest of the enterprise and does the report cover this question?

Dr. LA FOLLETTE. No. The report does not. As Nancy says, it does not emerge as a problem. The report did not cover that issue. I find it very intriguing. I would like to think about that one, the idea of linking the response to regulation to questions of liability and insurability. But we did not get into that question.

Mr. RITTER. I think it is coming. I think, in the same way, so many of the regulatory problems that have emerged now and are documented by this report have already been faced—and not necessarily dealt with effectively—out in the private sector and you can just see it just comes to the academic institutions a little bit later. But I think we are going to see it. For example, we are in the process of conferencing the Superfund law and the Superfund law has a right-to-know provision—on the House side in particular, the Edgar-Sikorsky provision—which covers a rather large universe of substances—I think something which may be a suspected carcinogen—and we are talking about, potentially, thousands upon thousands of substances, so many of which are in any chemistry laboratory, any physics laboratory, any electronics laboratory dealing with organic solvents or techniques of materials sciences. And it is going to be very interesting, how the—and the costs of response and how the universities will respond to a provision like this, if it is enacted into law, if it passes conference.

I would like to ask the question of—do you feel that public bodies and public citizens, in an era of what seems to be increasing technological illiteracy—not to speak of what we are hearing now about general illiteracy—how do you feel—can we—how much can we be involved as a highly sophisticated, scientific enterprise with a kind of public citizen intervention, something that is quite different from and unique to the—it is different from our foreign industrial competitors and unique somewhat to the United States? How far can we go? And, have we gone too far?

Dr. LA FOLLETTE. Have we gone too far? No. I think we have not gone far enough.

Mr. RITTER. But yet, we are the only industrial nation that has gone this far, and that has kind of stages of public intervention along the way in so many technological and scientific enterprises.

Dr. LA FOLLETTE. But I think that is in the spirit of the history of the Nation. Coming from a region where the town meeting still exists and town meetings are a viable form of discussion within communities, I think it continues to be within the political spirit of the United States to carry on discussions about issues which are often inherently political or social or moral issues.

Mr. RITTER. In your opinion, has the settlement of these disputes in these controversial case studies—has the settlement been rational with respect to, say, the views of the scientific community?

Dr. LA FOLLETTE. That is one that depends on who you talk to.

Mr. RITTER. Well, there is a kind of scientific consensus within the technical societies—within the professional societies.

Dr. LA FOLLETTE. On particular—on some issues—I think the feeling is that the resolution has been satisfactory. Certainly, on the recombinant DNA controversies, there is no evidence that the scientific community is widely dissatisfied with the outcome of that particular controversy.

There are particular—there are specific bones of contention. But, by and large, there is not a feeling that the scientific community was overburdened.

I am not speaking about the bureaucratic, the administrative burdens, but just, in general, that that was a controversy that was not satisfactorily resolved.

On certain other issues, I think there is often a feeling that the controversy has not been satisfactorily resolved, that the controversy has been resolved on other than technical issues.

Mr. RITTER. What were some of those examples?

Dr. LA FOLLETTE. I think—my impression is that, certainly, there is widespread feeling within the scientific community that the discussion on restrictions on the use of certain animals in experimentation is not one that is being resolved to the satisfaction of the scientific community.

I am not expressing that as a personal opinion, but there is that opinion within the community.

But I think that one of the difficulties is that the scientists and engineers—perhaps quite understandably—wish to resolve the issues on technical grounds, on technical estimates of risk or lack of risk, whereas the people who are involved see it as based on social and moral or political values and that we tend, in our regulatory system, to give more weight to the technical than to the social, moral and political. And when the conflicts of those values occur, then some of the parties are going to be left unsatisfied.

And because we have not—we have involved the public often, in a token way, in those discussions—members of the public then feel that they have been left out, that they have not been appropriately represented.

That is my impression from talking to some of the participants in the cases that we discussed in the OTA report that, had members—representatives—of the public been involved earlier in the controversy or in the discussions of siting of a particular research facility, that, perhaps the hostility that occurred later on might not have occurred, or the situation might have been diffused.

And some of that is, I think, a burden that should be rightly placed on the scientific and technical community for helping to educate the members of the affected public on the technical issues as well.

We are the experts on those technical issues. We have the responsibility to impart that knowledge. So there is a little more effort required on our part, if you will.

Mr. RITTER. So you feel that there should be a greater initiative on the part of the technical and professional community, the societies, the individuals involved in these two, to get out and seek some sort of public education process?

Dr. LA FOLLETTE. Yes. Because that is sort of the long-term, broad-based solution. And the more short-term solution would be to—in advisory bodies, in committees, in regulatory committees—to

involve more representatives of the community at large—more than just one representative because that representative may not cover all of the various affected areas.

Mr. RITTER. You feel that could somehow bridge an ideological opposition that may be out there? Some of this, you see, some of the public intervention, of course, is not—has an ideological component, as you know, and it may be representing national interest groups that have a certain tack to take and, you know, nuclear power could be a good example but it, I think, runs a much wider gamut.

Chemicals, of course, are coming into this realm today. Have you found that there are some brakes—B-R-A-K-E-S—on chemical research in universities that mirror some of the problems with——

Dr. LA FOLLETTE. Are the universities themselves?

Mr. RITTER. Mirror some of the problems with the chemical industry itself with Government regulation? Or hasn't that hit yet?

Dr. LA FOLLETTE. I suspect, from discussions that I have had, that the universities are just beginning to grapple with those issues. They are certainly, as you mentioned, beginning to grapple with the right-to-know laws and what those laws in States which have implemented them will have to face.

Mr. RITTER. One of the questions here was, is there a difference between that which goes on in a university laboratory and that which goes on in an industrial facility? The difference between—somebody mentioned it—the difference between a university and a steel mill?

The law is not going to make that distinction, I suspect, unless we write such law as to make that distinction.

Dr. LA FOLLETTE. Which would be one possibility, to include in—one hates to recommend making the legislation or the regulation even more complicated than it is, but perhaps that may well be required, to consider either exemptions or at least additional language for universities and for basic research.

Mr. RITTER. Thank you.

Thank you, Mr. Chairman.

Mr. FUQUA. Mr. Slaughter.

Mr. SLAUGHTER. No questions.

Mr. FUQUA. Mr. Packard.

Mr. PACKARD. I would defer to my colleague, Mr. Lewis. I am sorry I was not able to be here for your full testimony.

I think the concern that I would have and would like to ask about concerns the question of whether we are moving, trends are moving toward less and less regulation, more and more regulation—as it relates to scientific research—and what effect you see that will have on the scientific community in terms of research and development projects and programs?

Do you see us moving away from—there is a definite concern in the scientific world that regulations inhibit and proscribe their kinds of research programs, and that is true also in the private sector relative to industry—do you see us moving toward more and more regulation or less and less?

Dr. LA FOLLETTE. I think it is clear from our study that we are moving toward an era of more and more regulation. Researchers who are in their fifties, let us say, grew up and began doing their

science in an era when they were not as heavily regulated as they are today, so the situation has changed even within the scientific lifetimes of many of the most active members of the scientific and engineering research communities. So there is no question that there is more regulation.

What that will mean depends on the type of regulations that we are discussing. For regulations of process, and of communications, it may well have an inhibitory effect on the progress of scientific research.

Would you like to add something?

Ms. NAISMITH. Might I add to that?

Mr. FUQUA. Yes.

Ms. NAISMITH. In the context of this report, and other work that we have done, I would just like to state again one of the conclusions of the report, which is that, in a relatively short period of time, perhaps what has occurred is that instead of basic research—university research particularly—being regarded as almost a sequestered activity, a quiet, separate activity, there is now much more of a sense that it is part of, almost, the commerce of the society, a part of the activity that takes place, and that the kinds of concerns and issues that are raised with other types of activity are now raised with regard to science and research, and that we are in a period of redefinition in which the scientific community and the university community seek to come to terms with the new environment to find better ways to deal with issues of local intervention and issues of regulation.

A lot of this discussion this morning has had to do with how to devise a framework to operate in what we see as, certainly, a changed environment, and we see no reason to think that it is going to change back to the old environment, that we see that it is, as Dr. La Follette points out, it is cumulative and synergistic and begins to all work together.

Mr. PACKARD. Do you see that same trend moving in the same direction, and at the same pace in foreign research programs—comparatively speaking?

One of the concerns we are seeing more and more among the scientific community is that meeting more stringent regulations here in our country places them at a much less competitive ability with the foreign competitors—not only in the scientific world, but as that moves, as their research moves toward an actual product. The recapture of investment—and we are talking now about dollars—the investment in the research becomes a significant difference in the competitiveness on an international scale. Do you see the same trends in other foreign countries? Or do you see them moving at a different pace, or in a different direction?

Dr. LA FOLLETTE. Again, depending upon the particular nation involved, yes, we do see these kinds of discussions occurring elsewhere. Similar discussions on research involving genetic materials have occurred, animals, all the kinds of recombinant DNA controvers which occurred here which is occurring with much less, let us say, acrimony elsewhere. And, in general, people that I have met recently from European nations express a great deal of interest in the discussions of the task force, and seem to find these issues quite relevant to what they are beginning to experience.

Mr. RITTER. Would the gentleman yield?

Mr. PACKARD. I would be happy to yield.

Mr. RITTER. I think there is interest. And there is discussion. But I think what we have to recognize is that the scale of what actually impacts upon the regulatory process in the United States is orders of magnitude higher than anywhere else.

Now, it is starting to happen. The animal rights movement is very strong in England. But I think if you run the gamut of, you know, radiation, chemicals, and animals and anything that can possibly generate controversy, our system is set up to intervene within the process as opposed to simply in the discussion. And therefore, that the resulting regulations and the potential obstacles and potential costs are far higher here.

So I think part of the answer to Mr. Packard's question is, it is quite conceivable—as has happened with production of vaccines, for example, because of the liability questions—that we will export controversial areas of research as we have exported controversial areas of production and that this will hit the universities and the institutes later, but it is just a natural trend that they, too, will be involved with because they are subject and exposed to the same laws that have hit the industrial community.

I thank the gentleman for yielding.

Mr. PACKARD. That is my concern, that we may be driving out of this country some of the highly productive research into foreign countries simply because the regulatory environment is considerably different in other countries and that moves, not only from research and development, it moves to actual production of the effects of the research.

A very good illustration is in the nuclear energy field. We are simply not doing anything in this country, not only because of the high cost of regulation, but also because of the significant environmental pressures that are placed on the development of nuclear energy in this country. And now we find countries all around us that are developing their nuclear energy resources to the point where they are having 40, 50, 60 percent of their total energy output from nuclear resources. We see ours moving to virtually zero in this country. That places a significant disadvantage to competitiveness of businesses who have to pay a higher cost of energy compared to their foreign competitors. This is true in a multitude of areas. And so, as we talk and look at the regulations on research, it automatically needs to transfer to a product that ultimately is produced—and the requirement to recoup the cost of that increased regulatory effect on research and development.

And I wonder if that is not a—and I am not certain it has been addressed here—that that becomes a significant issue in terms of our own competitiveness? Our own labor market and our own productive market, simply have an increased cost of producing a product. And, in fact, a competitiveness. That, I guess, is where I tend to look more at what regulation is doing, is in terms of whether we are playing on an even field as it comes to the environment in other foreign countries.

Dr. LA FOLLETTE. Well, we know that in basic research, for example, a researcher—an individual researcher—may well balance the restrictions that are required on the process and procedures of re-

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search against the value of being in a system where communication is open and the collegial interaction necessary to the progress of his or her research can occur. So we do need to look at the question of regulation, certainly, when we are dealing with basic research, not necessarily with large industrial research, to look at it as a whole and to see that there is a balance going on.

Mr. RITTER. Will the gentleman yield?

I think we have a real advantage in this country because of the openness, because of the mobility within the scientific, intellectual community—the basic research community. That is an advantage the United States has, right now. I guess we would like to keep that advantage.

And you know, when you say, "Balance it," does that mean at some point you get to a level where your openness is 50 percent and that is the good news and your regulatory side is a countermanding 50 percent and that is the bad news? And then, the United States loses that competitive advantage as being the open, flexible, communicative, highly-mobile research society.

Mr. PACKARD. I think the question, I guess, that I would like to ask is, do we see, or have there been any studies done to evaluate the exporting of research simply related to regulation?

Dr. LA FOLLETTE. To the best of my knowledge, no.

Mr. PACKARD. Thank you, Mr. Chairman. I do not have any further questions.

Mr. FUQUA. Mr. Lewis.

Mr. LEWIS. Yes. I would just like to pursue this a little bit with the advantages that the United States has with openness, and the question of appropriate educational process for the public in other areas where we have the public response, as to the cost of science and how much should be invested, and they are also becoming part of the decisionmaking process.

We now find that the lack of indepth reporting by the media, that few people read the science journals or have the ability to read the science journals properly. We find that Senator Proxmire gives the Golden Fleece Award based on a 10-second exposé which is totally unfair in many, many cases. But what does the report cover and what do you recommend as to the general education of the public, so that we can keep the openness that we have, not lose the competability that we have, and still have the public behind the science community?

Dr. LA FOLLETTE. I think that we would go a great step toward that if we begin involving more members of the public in the discussions—as I said earlier in this discussion—and more members involved, realizing that they are going to act as nodes of communication and information for others in the community—and that the scientific societies or the professional societies have an additional role to play in the education of the public to bring these issues out in forums and in new publications, perhaps. But, more particularly, to foster a climate in which it becomes acceptable for the scientific community or members of the scientific community—scientists and engineers—to interact directly with the public and to discuss these issues.

We tend to reward, in the scientific and engineering communities, professional communication and not to reward communication

on technical issues to the public. Perhaps we need to be rethinking that.

Mr. LEWIS. I have a concern that the general public still feels that the scientist is a sequestered individual in a laboratory hidden back in a corner with a bunch of bottles and microscopes, and that sort of thing. And I think we have to open this closet and let the public recognize the tremendous advances that have been made. In fact, the chairman alluded to that the day before yesterday, in a speech, as to the tremendous advances just during this century, that it is unbelievable. But the public still does not recognize—and our space program is an example—they do not recognize the tremendous rewards that we, on the surface of the Earth, have received from the space program.

I just feel that we need an educational program for both sides, both for the science community, as well as comprehension by the public, and a greater interest generated by the public in the scientific advances in the research that we are doing.

Dr. LA FOLLETTE. One specific area would be in the communication of risk, because many of the regulations or many of the reactions of the particular communities are to a perception of risk. The engineering community tends to communicate risk in technical language, whereas the public, without the privilege of that education, may not understand what it means to run an X; or a Y; percentage risk of what the precise danger would be.

Mr. LEWIS. This is abundantly correct. I have attended lectures—I am an engineer, and I have difficulty understanding some of those lectures sometimes—and I just wonder, someone that does not have any exposure to this area at all, do they just get up and walk out, or just feel that they have wasted their time?

Mr. PACKARD. Would the gentleman yield for a moment?

Mr. LEWIS. Certainly.

Mr. PACKARD. I see a real dilemma in this whole area of risk. It seems that the scientific world—and a pure scientist—they are so engrossed in the benefits of their research that they do not really have a vision, perhaps, of the risks involved, nor does that concern them so much. Their concern is totally in a different direction.

The public, on the other hand, is just the opposite. They have no vision of the benefits of the research. Not parallel to the scientists. They cannot—in fact, often, our educational process simply does not convey what the potential benefits to society are. In fact, we often do not know that until long after the research is done, and it actually produces a product or a variety of products. Our space world is a very good example of that. So the public—and, particularly, the press—tends to dwell on the risks, and that often becomes a significant conflict in the emerging of scientific research. It often blocks it, and prevents it, and becomes an inhibitor, and that tends to force the scientist to go back into the closet, because they do not want to grapple with the regulations and with the pressures that come from the public.

I do not know what the answer is in trying to balance that out. I think the public tends to overreact to the risks. We see it all the time. And maybe one this very week, where there may be an overreaction to some of the products that are out in the marketplace.

Basic research is being inhibited—or at least the production of basic research may be overly done—because of the risks that the public does not seem to be able to equate with the benefits.

With us, we have to evaluate our dollar commitment on the basis of risk versus benefit. We have to evaluate almost everything we do here in Government in terms of benefit-to-risk ratio. The public does not have that ability to do it. The press does not do it. The scientist does not do it—on the other side of the coin. I do not know what the answer is in terms of trying to find a balance there, a workable balance.

I am sorry to take so much time, Mr. Lewis.

Mr. LEWIS. That is all right. You did fine.

Well, I do not want to belabor the situation. I just think it is so important that the scientists, and the scientific community themselves, recognize that they are not above this situation, that they have to get down one or two levels and work with the public in order to get the public behind them in a lot of the research that has to be done. I just hope that we do have education programs that can work to help the general public.

I think this is important, even if it has to be included in the budget for the overall scientific research program that we get down to—what we say a lot of times—the sixth-grade level so that everybody can understand exactly what is happening. And also open the doors of communication.

I know we get to hovering over our projects so many times and we feel that, again, we have the liability question as well as the copyright question and the patent question, again. But maybe we should be a little bit more open on some of the things we have done.

I guess I do not have a question. I do want to apologize for not being here for your presentation, Doctor.

Dr. LA FOLLETTE. There is a temptation to include here a plea for increases in the budgets for the science education programs at the NSF.

Mr. LEWIS. I think that is a very reasonable request.

Thank you, Mr. Chairman.

Mr. FUQUA. This almost leads me to a canned speech I used to give about understanding and misunderstanding, and I finally concluded that I was not convincing the world, so I gave up on it. Some people referred to it as "O-35" but that was just the number of the speech. We were in a conference several years ago, and Majority Leader Jim Wright was on the conference. It was on synthetic fuels, and about every day he would open the meeting, and Jim would give his speech about the importance of synthetic fuels. Finally, some of us suggested that, instead of listening to his speech again, that maybe he would just hold up a sign, you know, and call it "Old number 39," and we would all know what he was talking about, so mine kind of got a number assigned to it.

But it has been a very interesting report, Dr. La Follette, and we thank you very much for being here.

I think, as you can tell, there is a lot of interest in this subject, and it is one that does impact research, particularly within the regulatory environment.

Do we regulate enough to satisfy the public? Which is very important. And, in doing so, do we overregulate to stymie the researchers?

It is a very difficult area. I am not sure we will solve it here this morning, but it is one of deep thought and one that is certainly of great importance.

And we thank you for your contribution and not only for the report, but also for being here this morning and answering our questions and trying to enlighten us so that we better understand.

Dr. LA FOLLETTE. Thank you, Mr. Chairman.

Mr. FUQUA. We stand adjourned.

[Whereupon, at 9:53 a.m., the task force recessed to reconvene at 8:30 a.m. on February 27, 1986.]

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SCIENCE AND THE REGULATORY ENVIRONMENT

WEDNESDAY, MARCH 5, 1986

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
TASK FORCE ON SCIENCE POLICY,
Washington, DC.

The task force met, pursuant to call, at 8:30 a.m., in room 2325, Rayburn House Office Building, Hon. Don Fuqua (chairman of the task force) presiding.

Mr. FUQUA. We are very pleased to continue the hearings of our Science Policy Task Force on science and the regulatory environment, and we are very pleased to have Prof. Jon D. Miller, director of the Public Opinion Laboratory at Northern Illinois University.

And, Professor Miller, we would be pleased to hear from you at this time.

[A biographical sketch of Dr. Miller follows:]

DR. JON D. MILLER

Dr. Miller is Directer of the Public Opinion Laboratory and Professor of Political Science at Northern Illinois University. Professor Miller earned his baccalaureate in government at Ohio University in 1963, his M.A. in political science at the University of Chicago in 1965, and his Ph.D. in political science at Northwestern University in 1970. He is a member of Phi Beta Kappa and has been a Danforth Fellow.

Professor Miller had studied both adult and young adult attitudes toward science and technology for the last 15 years. He has authored two books *Citizenship in an Age of Science* and *The American People and Science Policy* and numerous articles and papers concerning the public understanding of science and technology. His work in the measurement of scientific and technological literacy is well known. He is a member of the Committee on the Public Understanding of Science and Technology of the American Association for the Advancement of Science and has served as a consultant to the National Science Foundation, the National Aeronautics and Space Administration, Time-Life, Monsanto, and other groups and corporations seeking to communicate scientific and technical information to the public.

STATEMENT OF DR. JON D. MILLER, DIRECTOR, PUBLIC OPINION LABORATORY, AND PROFESSOR OF POLITICAL SCIENCE, NORTHERN ILLINOIS UNIVERSITY, DeKALB, IL

Dr. MILLER. Thank you, Mr. Chairman. I am very pleased to be here this morning.

What I would like to do today is to talk about public attitudes toward the regulation of research in the United States. I will try to describe, from the perspective of a person who studies public attitudes, what the public thinks about the regulation of scientific research and also I will try to indicate, from the perspective of a po-

litical scientist, what are the implications of these attitudes for public policy.

As a starting point, let me differentiate between opinions and attitudes. Opinions are fragile and transitory dispositions toward objects or issues that are not central to the individual. Attitudes, in contrast, reflect more stable and continuing views on issues or objects of relatively high salience to the individual. In this context what I want to talk about today will focus on public attitudes toward the regulation of scientific research.

The basic difficulty is that most Americans do not have an attitude toward the regulation of scientific research, since science and technology are not high salience issues for most people in our society. This problem is not unique to science and technology, but occurs equally in areas like foreign policy, agricultural policy, educational policy, and virtually every major area of governmental activity. Beyond pervasive issues like inflation, taxes or the condition of the economy, most national political issues today are followed by only a minority segment of the population.

How then is public policy made in this type of specialized issue environment? In broad terms, I would argue, the initiation of policy discussions comes from a much smaller group of policy leaders, reflecting national organizations, sccieties and other interested groups. When these leaders are in agreement and when the decisionmakers agree, those people like ourselves and members of the committee and members of the Executive branch are in agreement, then by and large policy is made without broader public involvement. When policy leaders disagree among themselves or when decisionmakers do not concur with the requests of policy leaders, then various policy leaders seek to encourage wider public involvement and seek to mobilize those citizens who both have a high level of interest in an issue and those who feel sufficiently well informed about that issue. I refer to that segment of the public as the attentive public for science and technology. Likewise, there will be an attentive public for virtually every issue on the agenda.

Using this approach, I have estimated about one in four American adults are attentive to science policy issues, including the regulation of research. This attentive public includes about 39 million individuals. Persons with college educations and with occupations related to science and technology are somewhat overrepresented in the attentive public for science policy, but I would emphasize it is sufficiently large and diverse to include numerous citizens from all segments of our society.

Using this approach, I have studied both public attitudes toward science and technology and toward specific areas of regulation. In general, both the attentive public and the total public hold science and technology in high regard, believe that much of the present quality of life in the United States is attributable to science, and expect more beneficial results in the future. There is a high level of public confidence in the leadership of the scientific community.

In specific contexts, however, a significant segment of the public is willing to support the regulation of research. Both the attentive public and the total public expressed a relatively high level of concern about research that may involve the creation of new forms of plant or animal life. A substantial portion of the attentive public

and an even larger portion of the total public are willing to prohibit—I would say I would like to have seen that to say at least regulate—research directed toward the creation of new life forms. At the same time, the majority of Americans expressed the view that the present level of governmental regulation of genetic engineering is adequate.

I have, as I think you know, Mr. Chairman, provided to you a more detailed report that deals with some of these ambiguities in public thinking, and I will not elaborate on that now; but if you want to take it up in questions, that would be appropriate.

A study of the attitudes of science policy leaders—the point of initiation for most science policy matters—found a high level of satisfaction with the present level of governmental regulation of research. In regard to the regulation of basic scientific research, genetic engineering research and the development of new pharmaceutical products, approximately two-thirds of science policy leaders expressed support for the present level of governmental regulation. When current leadership attitudes are compared to an earlier leadership study about 3 years ago, it appears that there has been a growing consensus in favor of the present level of regulation over the last 3 or 4 years.

In summary, these results indicate that there is a high degree of consensus among science policy leaders accepting the present level of governmental involvement in scientific research. Two-thirds of science policy leaders support present regulatory policies toward basic scientific research. Over the last 3 years, individuals have moved from one position to another, but a strong consensus in support of the status quo remained throughout this period. In my view, it is unlikely that an initiative for a major change in the level of regulation of scientific research will emerge from science policy leaders in the foreseeable future.

The attitudes of science policy leaders are reflected in the attitudes of the attentive public for science policy. Both the attentive public and the general public hold science and technology in high regard, appreciate the quality of life improvements from science and technology, and hold ever higher expectations for the future. At present, and for the foreseeable future, there is broad leadership and public satisfaction with the current regulation of basic scientific research.

Up to this point, I have been describing the current structure and content of public attitudes toward the regulation of scientific research. It is also appropriate to ask if the levels of public interest, knowledge, and policy involvement is satisfactory within the framework of a society committed to democratic principles. In general terms, I would argue that the present level of public knowledge about science and technology is not adequate for the healthy functioning of a democratic political system.

The level of interest in science and technology matters is relatively high, but a substantial portion of American adults feel that they are not well informed about these areas. And numerous inquiries into the substance of what people actually know about science and technology indicates that by and large they are correct when they tell us they are poorly informed. In a study published in 1983, I estimated that only 7 percent of the American people were

scientifically literate, using what I think everybody would agree were relatively easy standards. If citizens in a democracy are to understand the debates on important public issues like nuclear power or genetic engineering, then they must be better informed than they are at the present time.

What can and should be done about the scientific and technological literacy of the American people? Let me make a few suggestions.

I believe that it is essential that we redouble our efforts to improve science and mathematics education in the United States. The Congress has provided important leadership in this area, and all of us who work in this field are grateful for the role the Congress has played in protecting and furthering science and mathematics education in this country. Yet, looking to the future, as efforts to control the size of the Federal deficit move forward, special care must be taken to recognize that science and mathematics education are essential to our long-term economic and political health.

Second, we must seek to make science and mathematics education available to all students. Looking back to the period after Sputnik when we last attempted a major stimulus of science and mathematics education in the United States, it appears to me that one of the messages we gave to too many students was that science and mathematics were only for the best and the brightest. Too many students elect not to enroll in science and mathematics courses because they think that the subject matter is beyond their ability. And in my view, that is a false assumption. Most people of normal intelligence can comprehend most of the major constructs needed to understand science and mathematics. There is broad agreement that since the 1940's the United States has produced the best trained scientists and engineers in the world. If you look at the international flow of students, the pathway is always to our door. Now I think it is time for us to begin to produce the most scientifically and technologically literate citizens in the world.

Finally, I would argue that it is important to recognize that learning about science and technology is a lifelong endeavor. When we think about science and mathematics education, we must not stop with the end of formal schooling. It is important to support museum programs, science programming for public television, and the provision of informal learning opportunities for adults. Over the last couple decades, there has been an extraordinary growth in the readership of science magazines and the viewership of science television and attendance at science museums. I think all of these indicators suggest that at least a substantial segment of the American people is ready and eager to receive more information about science and technology to try to update and keep current in their skills. It is important I think, however, to apply even greater creativity to this area and to build a stronger infrastructure for informal scientific education.

That completes my formal statement, Mr. Chairman.

[The prepared statement of Dr. Miller follows:]

Public Attitudes toward the Regulation of Research

A Presentation to the
Committee on Science and Technology,
U. S. House of Representatives

Jon D. Miller

Director
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March 5, 1986

PUBLIC ATTITUDES TOWARD THE REGULATION OF RESEARCH

The purpose of this presentation is to describe and analyze public attitudes toward the regulation of scientific research in the United States. I will try to describe -- from the perspective of a person who studies public attitudes -- what the public thinks about the regulation of scientific research and to indicate -- from the perspective of a political scientist -- the implications of public attitudes for the formulation of science policy.

As a starting point, let me differentiate between opinions and attitudes. Opinions are fragile and transitory dispositions toward objects or issues that are not central to the individual. Attitudes, in contrast, reflect more stable and continuing views on issues or objects of relatively high salience to the individual. In this context, this presentation will focus on public attitudes toward the regulation of scientific research.

The basic difficulty is that most Americans do not have an attitude toward the regulation of scientific research, since science and technology are not high salience issues for most people in our society. This problem is not unique to science and technology, but occurs equally in areas like foreign policy, argicultural policy, educational policy, and virtually every major area of governmental activity. Beyond per-

vasive issues like inflation, taxes, or the condition of the economy, most national political issues today are followed by only a minority segment of the population.

How is public policy made in this type of specialized issue environment? In broad terms, the initiation of policy discussions comes from a much smaller group of policy leaders, reflecting national organizations, societies, and other interested groups. When these leaders are in agreement and when decision-makers agree, policy is made without broader public involvement. When policy leaders disagree among themselves or when decision-makers do not concur with the requests of policy leaders, various policy leaders seek to encourage wider public involvement and seek to mobilize those citizens who both have a high level of interest in the area and who feel sufficiently well informed to have an attitude about the issue. This segment of the public is referred to as the attentive public for a given issue.

Using this model and several previously collected data sets, I have estimated that about one in four American adults are attentive to science policy issues, including the regulation of research. This attentive public includes about 39 million individuals. Persons with college educations and with occupations related to science or technology are somewhat over-represented in the attentive public for science policy, but it is sufficiently large and diverse to include numerous citizens from all segments of American society.

Using this approach, I have studied both public attitudes toward science and technology and toward specific areas of regulation. In general, both the attentive public and the total public hold science and technology in high regard, believe that much of the present quality of life in the United States is attributable to science, and expect more beneficial results in the future. There is a high level of public confidence in the leadership of the scientific community.

In specific contexts, however, a significant segment of the public is willing to support the regulation of research. Both the attentive public and the total public expressed a relatively high level of concern about research that may involve the creation of new forms of plant or animal life. A substantial portion of the attentive public and an even larger portion of the total public were willing to prohibit research directed toward the creation of new life forms. At the same time, a majority of Americans expressed the view that the present level of governmental regulation of genetic engineering research is adequate.

A study of the attitudes of science policy leaders -- the point of initiation for most science policy matters -- found a high level of satisfaction with the present level of governmental regulation of research. In regard to the regulation of basic scientific research, genetic engineering research, and the development of new pharmaceutical products, approximately two-thirds of science policy leaders expressed support for the

present level of governmental regulation. When current leadership attitudes are compared to an earlier leadership study, it appears that there has been a growing consensus in favor of the present level of regulation over the last four years.

In summary, these results indicate that there is a high degree of consensus among science policy leaders accepting the present level of government involvement in scientific research. Two-thirds of science policy leaders support present regulatory policies toward basic scientific research. Over the last three years, individuals have moved from one position to another, but a strong consensus in support of the status quo remained throughout this period. It is unlikely that an initiative for a major change in the level of regulation of scientific research will emerge from science policy leaders in the foreseeable future.

The attitudes of science policy leaders are reflected in the attitudes of the attentive public for science policy. Both the attentive public and the general public hold science and technology in high regard, appreciate the quality of life improvements from science and technology, and hold ever higher expectations for the future. At present, and for the foreseeable future, there is broad leadership and public satisfaction with the current regulation of basic scientific research in the United States.

Up to this point, I have been describing the current structure and content of public attitudes toward the regula-

tion of scientific research. It is also appropriate to ask if the levels of public interest, knowledge, and policy involvement is satisfactory within the framework of a society committed to democratic principles. In general terms, I would argue that the present level of public knowledge about science and technology is not adequate for the healthy functioning of a democratic political system.

The level of interest in science and technology matters is relatively high, but a substantial portion of American adults feel that they are not well informed about these areas. And numerous inquiries into the substance of what they know indicates that they are generally correct -- they are poorly informed about science and technology. In a study published in 1983, I estimated that only seven per cent of the American people were scientifically literate, using relatively easy standards. If citizens in a democracy are to understand the debates on important public issues like nuclear power or genetic engineering, then they must be better informed than they are at the present time.

What can, and should, be done about the scientific and technological literacy of the American people? Let me make a few suggestions.

First, it is essential that we redouble our efforts to improve science and mathematics education in the United States. The Congress has provided important leadership in this area and all of us who work in this field are grateful

for your efforts. Yet, looking to the future, as efforts to control the size of the federal deficit move forward, special care must be taken to recognize that science and mathematics education are essential to our long-term economic and political health.

Second, we must seek to make science and mathematics education available to all students. Looking back to the period after Sputnik when we last attempted a major stimulus of science and mathematics education in the United States, it appears to me that one of the messages that we gave to too many students was the these subjects were for only the best and the brightest. Too many students elect not to enroll in science and mathematics courses because they think that the subject matter is beyond their ability. In my view, that is a false assumption. Most people of normal intelligence can comprehend most of the major constructs needed to understand science and mathematics. There is broad agreement that since the 1940's, the United States has produced the best trained scientists and engineers in the world. Now, it is time to begin to produce the most scientifically and technologically literate citizens in the world.

Finally, it is important to recognize that learning about science and technology is a life long endeavor. When we think of science and mathematics education, we must not stop with the end of formal schooling. It is important to support museum programs, science programming for public television, and

the provision of informal learning opportunities for adults. The extraordinary growth in the readership of science magazines and the viewership of science television over the last decade demonstrate the demand by adults for this kind of information. It is important to apply even greater creativity to this area and to build a stronger infrastructure for informal science education.

Public Attitudes toward the Regulation of Research

A Presentation to the
Committee on Science and Technology,
U. S. House of Representatives

Jon D. Miller

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815-753-1901

March 6, 1986

EXECUTIVE SUMMARY

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INTRODUCTION

The purpose of this presentation is to describe and analyze public attitudes toward the regulation of scientific research in the United States. This morning, I will describe the public expectations of and concerns about scientific research, offer an interpretation of these data, and focus on the areas of primary public concern in regard to the control or regulation of scientific research.

The title of my presentation refers to "public attitudes." Often this term is used interchangably with "public opinion" and similar terms. As a starting point, it is important to provide a clear definition of what is meant by "public attitudes."

Hennessy (1972) has suggested that it is useful to distinguish among opinions, attitudes, and belief systems. In this classification, an opinion refers to a lightly-held, poorly-organized, disposition toward a person, issue, or object about which an individual has little interest and information. Most polling done primarily for newspaper or television syndication is correctly labelled as public opinion polling since these studies primarily tap "opinions."

In contrast, an "attitude" refers to a relatively enduring orientation toward a person, issue, or object, rooted in

an individual's interest and value structure. People have attitudes towards things they care about, that are important to them. While attitudes can and do change, they are substantially more stable than opinions.

Belief systems -- or ideologies -- are the highest level of logical organization found in individual orientations toward persons, issues, or objects. Marxism or fascism are extreme examples of belief systems, but the characteristic of an organizing theme that provides a comprehensive interpretation runs through all belief systems. While belief systems are interesting objects of study, they are relatively scarce in American society and are beyond the scope of this presentation.

Several scholars (McClosky, Hoffman, O'Hara, 1960; Converse, 1964; Hennessy, 1972) have argued that most Americans do not have political attitudes in the sense just defined. In unambiguous terms, Hennessy (1972) asserts

> Most people do not have political attitudes. Even in modern high-energy societies most people do not have political attitudes. When we accept that fact, and accept the epistemological and research implications that flow from it, we will be able to make more sense of attitude formation and change, of leader-follower relationships, and of the public policy making processes (p. 27).

THE SALIENCE OF SCIENCE POLICY ISSUES

The focus of this presentation will be public attitudes toward science generally and toward the regulation of scientific research in particular. In the context of the Hennessy-Converse arguments discussed above, it is reasonable to ask how many Americans have what could be called an atttitude toward science? It is not an easy question to answer. What is the empirical evidence?

Here, we encounter the first of several points at which substance and method are entwined. How can we determine whether a person has an opinion or an attitude toward a science policy issue? We could look at the number of people in national surveys who tell us that they don't or can't give an answer to survey items involving science. For example, looking at a question like "Overall, would you say that science and technology do more good than harm, more harm than good, or about the same amount of each?", national survey results collected by the Opinion Research Corporation (1972, 1974, 1976) indicated that about 90 per cent of their respondents could answer this question. The same question has been repeated more recently by Cambridge Reports and about 95 per cent of their respondents were able to answer the query (National Science Board, 1985). Should we conclude from this that 90 or

more per cent of the American public has an attitude toward science and technology?

I think not. Survey researchers have demonstrated repeatedly that respondents will attempt to be cooperative and to respond to questions about which they have little interest or information. Many respondents with only an "opinion" in Hennessy's terms would be likely to pick one of the three choices offered by the question rather than admit their lack of knowledge on the topic. It would appear that a closed-ended question of this type is not a good estimator of the proportion of adults holding an attitude toward science and technology.

On the other hand, existing data bases include very few open-ended items pertaining to science and technology. A 1979 national survey designed by Miller and Prewitt (Miller, Prewitt, Pearson, 1980) did include a couple of items that were open-ended. Unfortunately, these items focused on substantive knowledge (What does it mean to study something scientifically?) and would provide unrealistically low estimators of the existence of attitudes toward science and technology.

Recalling Hennessy's suggestion that an attitude would probably reflect a continuing interest in a topic, another approach to estimating the existence of attitudes toward science and technology might utilize interest inventories if they included science and technology items. Surveys conducted by Miller and Prewitt for the National Science Board in 1979 and

by Miller in 1981 and 1985 did include a set of nine interest items, with one item focusing on science and one on technology. In these surveys, each respondent was read a list of issues that might have been found in a newspaper or magazine and asked to classify himself or herself as "very interested, moderately interested, or not at all interested" in each of nine issue areas. One area was "issues about new scientific discoveries" and another was "issues about the use of new inventions and technologies." The same interest battery was repeated by Miller in other national surveys completed in 1983 and 1985.

While each of these items is a closed-ended trichotomy, the methodology problems are somewhat less serious in the estimation of a magnitude. In questions of this type, respondents who do not feel strongly about an area or may not have even thought about it are likely to give the middle -- or moderate -- response. To give a "very interested" or "not at all interested" reply would be to take a more extreme position and respondents who do not feel an attraction to an issue are unlikely to select an extreme choice.

An examination of these data indicated that the level of interest in both new scientific discoveries and the use of new inventions and technologies has been increasing in recent years, with at least 40 per cent of the American people expressing a high level of interest by 1983. While the proportion of the public that was very interested in new scientific

discoveries or the use of new technologies was lower than the proportion that followed economic issues, it was significantly larger than the proportion interested in foreign policy matters.

TABLE 1

Public Interest in Selected Policy Areas: 1979-85

	"very interested in ..."			
	1979	1981	1983	1985
Economic issues & business conditions	35%	54%	58%	49%
Issues about new scientific discoveries	36	38	49	46
Issues about the use of new inventions and technologies	33	34	45	40
Issues about energy policy	47	50	40	37
Issues about space exploration	NA	26	29	31
International & foreign policy issues	22	36	30	35
Local school issues	38	46	46	48
Argicultural & farming issues	23	24	NA	30
Issues about new medical discoveries	NA	NA	NA	69
N =	1635	3195	1630	1992

The real issue with these data is whether we are willing to accept interest as an indicator of holding an attitude or set of attitudes toward science and technology. Interest may spring from a strong sense of curiosity, from some background knowledge or training, or from an awe of the mysterious.

While some individuals who express a high level of interest in science or technology based on curiosity or awe may hold some general attitudes about the ability of science to solve problems or about the future results of science, it is unlikely that a person who does not feel reasonably well informed about science and technology would be able to formulate or maintain very concrete science policy attitudes. In short, the combination of a high level of interest and the perception of a reasonable level of knowledge may be a useful estimator of the proportion of the public that holds attitudes toward science and technology in Hennessy's terms.

The combination of a high level of interest in an issue and the perception of being adequately informed also defines the basic dimensions of an attentive public, following the work of Almond (1950), Rosenau (1974), and Miller (1983a). In all societies, time is a finite commodity for each individual and in modern industrial or post-industrial societies like the United States, there is considerable competition for each individual's time. Most individuals living in a larger metropolitan area in the United States now can elect to spend his or her time watching an extensive array of films on television or in theaters, attending or watching numerous professional and collegiate sporting events, engaging in a wide array of personal recreation or fitness activities, dining, shopping, or studying at a variety of levels. The individual's decision to be concerned about public affairs generally and science

policy in particular must be viewed in the context of this ongoing competition for time. We will return to the policy participation role of those citizens who do elect to follow science policy matters at a later point in this analysis.

For our purposes, it appears that the attentive public for science policy may be the best indicator of the proportion of the public that has an "attitude" toward science and technology issues. An analysis of several previous data sets indicates that the proportion of the public that is attentive to science policy issues has been increasing steadily since the 1950's and that almost a quarter of American adults could be classified as attentive to science policy by 1985 (see Table 2). These survey data suggest that attentiveness to science policy is reasonably broadly spread across all segments of American society. Males are slightly more likely to be attentive than females, but about one in five American women were attentive to science issues in 1985. Similarly, college graduates were significantly more likely to be attentive to science issues than citizens without a college degree, but about one in five Americans with a high school diploma or less were also attentive to science issues.

From these data, we may conclude that science policy issues are salient to approximately one in four American adults. Following Hennessy's argument about the distribution of political attitudes among the American people, it would appear that about a quarter of the adult population in the United States

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TABLE 2

The Attentive Public for Science Policy: 1957-1985

	Attentive Public					N				
	1957	1979	1981	1983	1985	1957	1979	1981	1983	1985
Total	10%	19%	20%	25%	23%	1919	1635	3195	1630	1992
Age										
21-34	11	19	21	23	20	584	508	1068	554	687
35-54	10	20	19	26	24	853	492	1033	480	609
55+	7	17	19	26	24	470	473	843	479	579
Gender										
Female	9	15	15	21	18	1091	777	1568	799	1045
Male	10	23	25	29	27	828	696	1375	715	947
Education										
LT HS	5	9	10	17	11	1060	443	552	268	262
HS Grad	16	19	19	23	22	678	790	1746	830	1217
Coll Grad	13	48	30	35	30	144	238	645	415	511

might be expected to hold some attitudes toward science policy matters. Some of these atttitudes will be at a very general level, expressing a high level of faith in the future achievements of science and technology. Others may focus on one or two specific controversies involving science or technology -- the nuclear power controversy, the use of animals in experiments, or the development of specific medical technologies -- without integrating those specific policy preferences into a larger network of attitudes toward science. We would expect to find an attitude toward science or technology among those

citizens who are not attentive to science issues in only the rarest of cases.

IMPLICATIONS FOR THE FORMULATION OF SCIENCE POLICY

If only a quarter of the American people can be said to hold attitudes toward science policy issues, what are the implications of this conclusion for the formulation of science policy in the context of the democratic and participatory norms that have characterized the American political system? Is science policy to be exempted from the normal democratic procedures? The answer depends on an understanding of the process of policy formulation under conditions of political specialization.

The need for specialization in modern political systems springs from the scope and complexity of government in industrialized nations in the 20th century. Can any citizen be expected to follow and maintain an adequate information base about foreign policy issues, argicultural policy issues, transportation policy disputes, the condition of the economy, the balance of trade, current problems in law enforcement, education policy issues, and science policy issues? When the range of state and local issues are added to this list, it is apparent that no individual can be expected to follow every major public policy issue.

The political specialization process involves two sets of decisions by the individual citizen. First, each citizen must

decide whether to invest some portion of his or her time to political activities at all. Over the last three decades, an increasing proportion of Americans have decided to focus their energies on non-political activities. This result is reflected most visibly in the turnout for presidential elections, but it is also apparent in voting for congressional, state, and local offices and in participation in voluntary organizations with a high level of political activity.

Second, among those citizens who elect to follow public affairs, it is necessary to select those issues or areas in which the individual can become and remain reasonably well informed. This decision is often referred to as issue specialization. Most often, this decision is not one of conscious consideration of alternatives, but rather the gradual and inadvertent development of areas of interest, based on educational, occupational, and personal experiences. Previous studies (Miller, Prewitt, Pearson, 1980; Miller, 1982a, 1983a) have found that about half of the American public is attentive to at least one national issue area. Among those citizens who follow one or more public policy areas, the modal number of issue areas is two. This result suggests that the distribution of issue attentiveness is more pluralist than elitist.

How, then, do the attitudes of those citizens who are attentive to science policy make their way into the policy formulation process? Almond (1950) provided a basic model 35 years ago in his pioneering studies of public attitudes toward

foreign policy. Almond outlined a stratified model of policy formulation in low saliency -- or non-electoral -- issues. Pyramidal in form, the model identifies a small group of decision-makers who have the power to make binding decisions in a given issue area. In the case of science policy, the decision-makers would include the President, the major cabinet and agency heads with responsibilities in the area of science, the leadership of Congress, and the members of key committees involved in the formulation of science policy. On occasion, a federal judicial officer may play a decision-making role.

At a second level in the model, much of the policy initiation and debate about policy issues comes from a group of science policy leaders. The leadership group would include the officers of national scientific and professional societies, the officers of major corporations involved in science and engineering, winners of scientific honors like the Nobel Prize, persons who provide testimony to congressional committees or who serve on department level advisory committees in executive agencies, and science journalists with national distribution media. Miller (1983a) has estimated that there are about 3500 science policy leaders in the United States at the present time.

Most of the debate about science policy issues occurs among science policy leaders and between these leaders and the decision-makers. When there is agreement between the leadership group and the decision-makers, policy is made and there

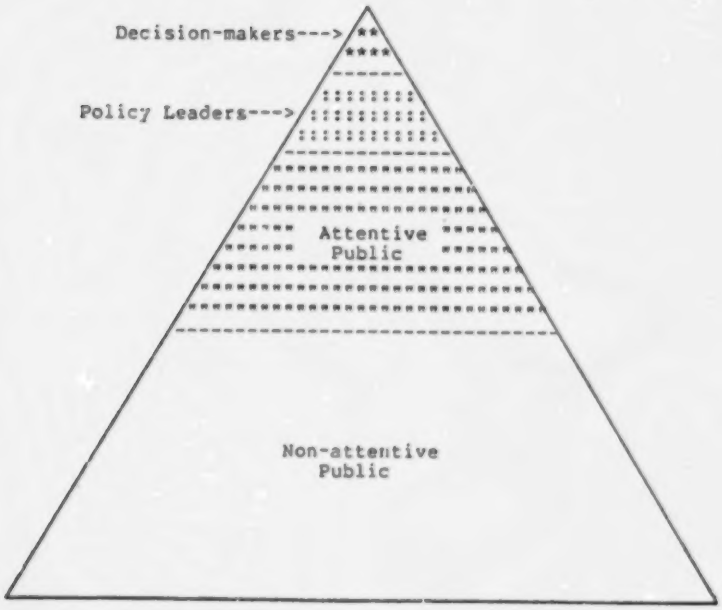

Figure 1: A Stratified Model of Science Policy Formulation

is no wider public involvement in the process. Most science policy issues in the United States are decided in this manner. This is not unique to science policy. Most issues involving foreign policy, economic policy, or agricultural policy are resolved between the leadership groups in those areas and their respective decision-makers.

There are two situations in which the attentive public for science policy may become involved and one situation in which the total electorate may become involved in the policy making process. When there is a division of policy preferences among the science policy leadership group itself, there is usually an appeal to a wider public to intervene in the process and to exercise influence by contacting decision-makers directly. The controversy over the use of nuclear power to generate electricity is a good example of this process. Some scientific and engineering leaders have taken strong stands in favor of nuclear power and others have taken equally strong stands against it. Both groups have attempted to enlist other citizens in the process, asking for people to sign petitions or call or write selected office holders. Most of the appeals by leadership groups are directed to those citizens who they believe have some interest in the issue and who know enough about it to be able to make an intelligent contact on the issue, that is, the attentive public.

A second situation involving wider public participation occurs when there is a difference in policy preferences be-

tween the science policy leadership and one or more sets of major decision-makers. The recent controversy over the funding of science education is an example. The incoming Reagan Administration recommended the elimination of science education funding in the National Science Foundation budget and was able to achieve that result in the fiscal year 1982 budget. There was broad agreement among science policy leaders that funding for science education was important and the leadership groups organized significant direct contact by citizens attentive to science issues with decision-makers. As a result, a bi-partisan group of congressional leaders worked together to restore science education funding in the NSF budget.

Finally, in some cases, an issue may become sufficiently controversial that there is public pressure to open the decision-making process to wider participation. The petition for a direct referendum on an issue is one method by which this can be done. The initiation of direct referenda on nuclear power plants at the state level is a good illustration of this process. Once a scientific or technical issue is placed on a general election ballot, the policy formulation process has been expanded to include the wider public -- attentive and non-attentive alike. To date, the conversion of scientific and technical issues into electoral issues has occurred only at the state and local levels.

With the exception of direct referenda, those citizens who are not attentive to science policy issues are unlikely to become involved in the formulation of science policy. Many of

the people in this group have decided -- at least temporarily -- to abstain from the political process and others have active interests in issues other than science policy. In a democratic political system, however, it is important to understand that the broader public always retains a political veto and can intervene through the election of decision-makers if there were sufficient public discontent over any issue or event. The public never surrenders its final power, but rather delegates it to those citizens who have a high level of interest and knowledge about a given issue area.

IMPLICATIONS FOR THE STUDY OF PUBLIC ATTITUDES

Given the distribution of attitudes toward science suggested by Hennessy and the political specialization process outlined above, what are the implications of these models for the study of public attitudes toward science generally and toward the regulation of scientific research specifically? —Two conclusions emerge.

First, when looking at both the previous literature and in re-examining existing data sets, it will be important to try to identify the policy views of those citizens who are likely to have attitudes toward science policy. While it may also be interesting to look at the views of other groups, it is important to recognize that not all citizens have an equal likelihood of actually participating in the science policy process. This is not a normative judgment about who should participate, but rather an empirical description of who has

participated in previous scientific controversies and who is behaviorally the most likely to participate in the formulation of science policy in the future.

Second, the models reviewed above suggest that it will be important to understand the atttiudes of science policy leaders, especially in regard to the regulation of scientific research. As suggested above, new policy ideas are almost always initiated by one or more policy leaders and much of the debate about specific policy matters occurs within this group. To fully understand the environment for science in the United States, it will be essential to understand the policy preferences of science policy leaders.

Fortunately, a substantial portion of the literature and several existing data sets have the variables necessary to make appropriate stratifications of public attitudes toward science. In addition, there are some recent data available concerning the policy views of science policy leaders concerning the regulation of scientific research and selected areas of technological research. Using this frame of reference, it is now appropriate to turn to an examination of the attitudinal environment for science in the United States, the specific policy views of interested and informed citizens about the regulation of scientific research, and the views of science policy leaders concerning the regulation of basic and applied research.

THE ATTITUDINAL ENVIRONMENT FOR SCIENCE

The attitudinal environment for science includes the attitudes of the public toward science and technology in general or institutional terms. These attitudes may be usefully grouped as hopes and expectations, reservations and concerns, confidence in the leadership of the scientific community, and specific regulatory attitudes.

HOPES AND EXPECTATIONS

In broad strokes, the literature and the data from the four decades since the end of the Second World War portray a public that has a high regard for the past achievements of science and technology and high hopes for even more spectacular results in the future. Even though science is still seen as a magic black box by most Americans (Miller, 1983b), the evidence is clear that most Americans believe that their current standard of living is in large part the result of modern science and technology. The substantial gains in medical science symbolizes the achievements of science for most Americans.

The first national study of public attitudes toward science in the post-war years was conducted by the Survey Research Center of the University of Michigan in the fall of

1957. Sponsored by the National Association of Science Writers and the Rockefeller Foundation, the study was designed to assess the public's interest in and knowledge about science and technology, the major sources of information on current science issues, and the appetite of the public for science news. The study included personal interviews with a national probability sample of 1919 adults and the field work was completed in early October, 1957, just two weeks prior to the launching of Sputnik I. Inadvertently, the 1957 NASW study became the only existing set of measures of the attitudes of the American public toward science prior to the beginning of what is often termed the Space Age. The study offers a unique opportunity to look back to the calm of the mid-50's.

The 1957 NASW study found a public that believed that science and technology had won the war, created "miracle" drugs, and would continue to produce a cornucopia of benefits for American society (Davis, 1958). Almost 90 per cent of American adults in 1957 said that the world was "better off because of science." When asked why they thought so, slightly more than half cited medical advances and about 40 per cent pointed to the American standard of living. When asked to name some potential "bad effects" of science, 90 per cent of the adults in the study could not think of a single possible negative effect. A full 94 per cent of the population were willing to agree that science was making their lives "healthier, easier, and more comfortable." Ninty per cent agreed that

"most scientists want to work on things that will make life better for the average person" and 88 per cent felt that science was "the main reason for our rapid progress." It would be hard to imagine a more supportive public.

Despite the influence of the space race and the continued growth of post-war science and technology, there were few efforts made in the 1960's to measure public attitudes toward science. The next systematic effort to assess the attitudes of the American people toward science and technology was initiated by the National Science Board in 1972. As a part of its new Science Indicators series, the NSB decided to include a chapter on public attitudes toward science. The NSB staff prepared a set of questions and used the Opinion Research Corporation (ORC) caravan to collect national data sets in 1972, 1974, and 1976.

These NSB surveys found a public that still held science and technology in high regard, although less so than in 1957. In contrast to the almost 90 per cent of the public that thought in 1957 that the world was "better off" because of science, only 70 per cent of the public held the same view in 1972 (NSB, 1973). Similar results[1] were obtained in the 1974 and 1976 studies (NSB, 1975, 1977). While the absolute level

[1] It is important to note that the percentage of those willing to say that the world was worse off because of science did not increase significantly from 1957, but the percentage of persons who were uncertain, undecided, or felt that they were about equal did increase substantially over the 15 year period spanned by the four studies. It would be correct the characterize these results as marking an increase in wariness rather than the growth of anti-science attitudes.

was down somewhat, a substantial majority of the total public held very positive views of the contributions of science to American society.

In a 1979 national study of public attitudes toward science and technology sponsored by the NSB, several of the 1957 questions were repeated, offering an opportunity for comparison across two decades. In 1979, 81 per cent of the public still agreed that scientific discoveries were making their lives "healthier, easier, and more comfortable" and 86 per cent expressed the view that scientific discoveries were "largely responsible" for the standard of living in the United States (Miller, Prewitt, Pearson, 1980). In a comparable national study in 1983, Miller (1983c) found that 85 per cent of American adults continued to agree that science made their lives healthier, easier, and more comfortable.

While the material gains attributable to science have undoubtedly influenced public attitudes toward science, there is evidence that Americans have a commitment to the value of science per se. In a 1983 national survey, Harris (1984) found that 82 per cent of American adults agreed that scientific research "which advanced the frontiers of knowledge" was worth supporting "even if it brings no immediate benefits." Only 14 per cent of Americans rejected this idea.

Evidence from the European Barometer indicates that western Europeans hold very similar views about the positive contributions of science and technology to their standard of liv-

ing (Rabier, 1981). Approximately three-quarters of western Europeans were willing to agree with a statement that science had been and would continue to be a major factor in improving their lives. There was a high degree on consensus among countries, ranging from 80 per cent in Northern Ireland to 65 per cent in the Netherlands.

TABLE 3

European Attitudes toward Science: 1978

Country	Per Cent Agree
Northern Ireland	80%
United Kingdom	79
Italy	76
France	75
Ireland	75
West Germany	71
Luxembourg	70
Denmark	67
Belgium	66
Netherlands	65

"Science will continue in the future as it has done in the past to be one of the most important factors in improving our lives."

Another facet of the attitudinal environment for science is reflected by the public's expectations for future achievements. The belief that science has contributed to the health and comfort of the society is inherently retrospective. It is important to inquire whether the public expects similar achievement from science in the future, or whether the public

thinks that the frontiers of science have been explored as thoroughly as the geographic frontiers of our continent. Beginning with the 1979 study for the NSB, one series of questions have asked the public to assess how likely it is that science will achieve certain results in the next 25 years. The results indicate that a large segment of the public holds high expectations for future outcomes from science and technology. A majority of the public believe that it is "very likely" that within the next 25 years science will find a cure for the common forms of cancer, have people working in a space station, and find efficient sources of cheap energy (see Table 4).

In contrast, a substantial portion of the public does not expect expect science to be able to cure mental retardation, communicate with alien beings, or put whole communities of people into outer space. These results indicate that the public does have some ability to differentiate between likely and less likely outcomes and that the optimism found in several previous responses is not a simple yea-saying reaction.

From these aggregate results, it would appear that a significant portion of the American people hold positive general attitudes toward science. Recalling the earlier discussions of the existence of attitudes toward science and impact of political specialization, it is important to inquire whether the attentive public for science policy shares these same positive views of the past and future results of science. Fortunately,

TABLE 4

Expectations for Future Scientific Achievements: 1979-83

Percent saying that the following results will be achieved in the next 25 years:	Year	Very likely	Possible but not too likely	Not likely at all	N
a cure for the common forms of cancer.	1979	46	44	8	1635
	1983	57	36	6	1630
	1985	57	36	6	1992
a cure for mental retardation.	1983	11	40	47	1630
a way to put communities of people in outer space.	1979	17	38	42	1635
people working in a space station.	1983	52	34	12	1630
the placement of a scientific or mining colony on the moon.	1985	33	41	24	1992
more efficient sources of cheap energy.	1979	57	34	7	1635
a safe method of disposing of nuclear wastes.	1983	29	41	26	1630
	1985	36	42	18	1992

"Now, let me ask you to think about the long-term future. I am going to read you a list of possible scientific results and ask you how likely you think it is that each of these will be achieved in the next 25 years or so."

national data sets collected in 1957, 1979, 1981, 1983, and 1985 are available for re-tabulation for this purpose.

The one question relevant to this analysis that has been asked repeatedly throughout the last three decades has been the agree-disagree statement concerning the contribution of

science to making our lives "healthier, easier, and more comfortable." A re-tabulation of previous studies indicates that there has been some decline in the proportion of both the attentive public and other citizens willing to agree with the statement, but nine of ten members of the attentive public for science policy and eight of ten other Americans still hold that belief (see Table 5).

TABLE 5

Attitude toward Contribution of Science, by Attentiveness: 1957-83

	Attentive Public	Other Citizens	N Attn.	N Not
Per cent agreeing that science makes our lives healthier, easier, and more comfortable.				
1957	98%	93%	183	1736
1979	89	79	232	1313
1983	92	82	398	1232
1985	92	87	447	1545

Some of the more recent data sets allow an examination of the difference in expectations between those who follow science policy matters and those who do not. In general, persons who were attentive to science policy issues were more optimistic about the future achievements of science and technology than were other citizens (see Table 6).

TABLE 6

Expectation for Future Achievements, by Attentiveness: 1979-83

Percent saying it is "very likely" that the following results will be achieved in the next 25 years:	Year	Attentive Public	Other Citizens
a cure for the common forms of cancer.	1979	55%	44%
	1983	68	54
	1985	63	55
a cure for mental retardation.	1983	13	10
a way to put communities of people in outer space.	1979	27	14
people working in a space station.	1983	62	49
the placement of a scientific or mining colony on the moon.	1985	38	31
more efficient sources of cheap energy.	1979	76	53
a safe method of disposing of nuclear wastes.	1983	35	27
	1985	41	35
N (1979) =		307	1328
N (1983) =		398	1232
N (1985) =		447	1992

"Now, let me ask you to think about the long-term future. I am going to read you a list of possible scientific results and ask you how likely you think it is that each of these will be achieved in the next 25 years or so."

In summary, both the existing literature and selected re-

tabulation of available data indicate that most Americans have a positive image of science and of scientific research. Those citizens who have a high level of interest in science and who feel reasonably well informed about it tend to hold even more positive views about the past and future benefits of science than other citizens.

RESERVATIONS AND CONCERNS

Throughout the post-war years, there has been some level of wariness about some of the possible negative effects of science among a substantial minority of the American people. On balance, these reservations have not offset the high levels of positive affect and expectation described above, but it is necessary to review and understand the magnitude and substance of these attitudes.

The 1957 NASW study found some reservations about the effects of science, but it was muted and most often accepted as the price of gaining good things from science. Slightly over 40 per cent of the public was willing to agree that science "makes our way of life change too fast" and 23 per cent agreed with the statement that "one of the bad effects of science is that it breaks down people's ideas of right and wrong." Although 70 per cent of the adults in the 1957 study agreed that "the things that happen in this world are mostly controlled by God" and about half felt that "one of our big troubles is that we depend too much on science and not enough on faith," when

asked to assess the net effect, nine of ten concluded that the world was better off because of science. There was some wariness, but not enough to offset the desire for increased health and comfort.

Oppenheim (1966) repeated some of the 1957 NASW items in a national survey conducted by the National Opinion Research Center in 1964 and found that the level of public wariness or concern was increasing. The NSB-sponsored studies in the early 1970's found the same trend. A comparison of the 1957 results with a 1985 study just completed by the Public Opinion Laboratory indicates that these reservations have remained largely unchanged over the last quarter century.

The tension between science and religion continues, with half of the adult population in both years agreeing that we "depend too much on science and not enough on faith" (see Table 7). By 1985, a third of the adult population of the United States was also willing to endorse the statement that one of the "bad effects of science" is that it breaks down people's ideas of "right and wrong." These are surprising results in that the demographic profile of the American people has shifted dramatically over the last 28 years to include substantially more college graduates and persons who are exposed to science in their occupations.

The concern over the impact of science on the pace of change in society has also continued at virtually the same level. In both years, approximately four in ten Americans ex-

pressed some concern that science causes our lives to "change too fast" (see Table 7).

TABLE 7

Public Concerns about Science: 1957-1985

	Year	
	1957	1985
We depend too much on science and not enough on faith.	50%	54%
One trouble with science is that it makes our way of life change too fast.	43	41
One of the bad effects of science is that it breaks down people's ideas of right and wrong.	23	33
N =	1919	1992

Recent studies indicate a renewed concern about the tie between science and weapons. A 1983 national survey by Harris (1984) found that 74 per cent of adults in the United States were willing to agree with the statement that "with the development of nuclear, chemical, and biological weapons, science and technology may end up destroying the human race." A 1985 study found that 12 per cent of the adult population thought that it was "very likely" that warfare would extend to space in the next 25 years and an additional 34 per cent of the American people thought that space wars were "possible."

Given the previous discussion of the likelihood of finding firm attitudes among the attentive public but only opinions among other segments of the population, it is appropriate to inquire whether the attentive public holds the same kinds of reservations reflected in these national survey results. A re-tabulation of the 1957 and 1985 data indicated that the attentive public holds many of the same reservations found in the previous data, but that the proportion of persons holding those reservations is slightly lower among the attentive public than other citizens (see Table 8). Although about half of attentives were concerned that we depend too much on science and not enough on faith, only a quarter felt that science tended to break down people's ideas of right and wrong. The proportion of attentives concerned about changes in the pace of life was significantly lower than the proportion for other citizens in both years.

In summary, it appears that a substantial portion of the American people hold some reservations about the impact of science on society. In the context of the very positive views noted previously, it would appear that a significant portion of the American people recognize and understand that science involves both the potential for substantial benefits and the possibility of damage or misuse.

TABLE 8

Concerns about Science, by Attentiveness: 1957-85

Per cent agreeing that ...	Attentive 1957	Attentive 1985	Other Citizens 1957	Other Citizens 1985
We depend too much on science and not enough on faith.	44%	47%	50%	56%
One trouble with science is that it makes our way of life change too fast.	34	33	44	43
One of the bad effects of science is that it breaks down people's ideas of right and wrong.	16	25	24	36
N =	183	447	1736	1545

CONFIDENCE IN SCIENCE

Given the combination of positive hopes and expectations and the simultaneous level of concern, how does the public reconcile these attitudes? Is there an overall view of science? In general terms, attitude research from the last three decades indicates that the American people believe that the benefits of scientific research outweigh its potential harms and trust the leadership of organized science in the United States. Let us look at some of the previous studies and empirical evidence in support of this conclusion.

As noted earlier, 88 per cent of the adults studied in 1957 reported that they felt that the world was better off because of science (Davis, 1958). Beginning in the 1970's, the

surveys sponsored by the NSB asked each respondent to make an assessment of the relative benefits and harms and to weigh the two. Similar questions have been asked since that time by Cambridge Reports (NSB, 1985). The data indicate that a solid majority of Americans believe that science does more good than harm (see Table 9). Only about one in 20 Americans believe that science does more harm than good, but about a third of Ameican adults are unsure as to where the balance falls. Some of this uncertainty may reflect a lack of interest or information.

TABLE 9

Public Assessment of the Risks and Benefits of Science: 1972-85

Science & technology...	do more good than harm	do more harm than good	about the same amount of each	don't know/ not sure	N
1972	54	4	31	11	2209
1974	57	2	31	10	2074
1976	52	4	37	7	2108
1983	73	3	21	3	1466
1984	63	5	27	5	1864
1985	58	5	32	5	1866

"Overall, would you say that science and technology do more good than harm, more harm than good, or about the same amount of each?"

SOURCES: Opinion Research Corporation (1972, 1974, 1976), Cambridge Reports (1983, 1984, 1985).

Although the exact items discussed above have not been used in a survey that would allow the separation of attentives and other citizens for analysis purposes, the most recent Public Opinion Laboratory study did include two items that reflect the same attitude. Each respondent was asked:

> People have frequently noted that scientific research has produced both beneficial and harmful consequences. Would you say that, on balance, the benefits of scientific research have outweighed the harmful results, or that the harmful results of scientific research have outweighed its benefits?

Eighty-two per cent of the attentive public expressed the view that the benefits of scientific research outweighed its harmful results in comparison to 71 per cent of other citizens. These results suggest that those citizens who are interested in science issues and who follow science policy matters believe that the benefits of science outweigh its potential harm. This same view is reflected in the larger public, but it is not likely to be as solidly rooted in the larger population as it would be in the attentive public.

A second approach to reconciling the potential for good and harm from science is reflected in the measures of confidence in the leadership of organized science. As noted in the discussion concerning political specialization, most Americans have considerable pressure on their time and do not normally set aside a significant portion of time to consider the flow of issues in areas like science policy. If citizens -- especially those attentive to science -- have confidence in the leadership of major scientific organizations and corporations,

then the leaders can be relied on to monitor the process and the citizen can wait until a real controversy emerges before becoming concerned about the issue.

The evidence from the General Social Survey (Davis and Smith, 1984) indicates that the leadership of the scientific community has been and continues to be held in high esteem (see Table 10). The only major institution in American society that has consistently claimed a high level of confidence from more Americans has been medicine, which is closely related to the scientific community.

In summary, most Americans see the benefits of science as greater than any potential harms or risks. This view is held even more firmly by the attentive public for science policy. In addition to the positive assessment of the risks and benefits of science, the evidence indicates that the leadership of the scientific community is held in high regard, implying a degree of trust in their monitoring of the work of organized science.

TABLE 10

Public Confidence in Science and Selected Other Institutions: 1973-84

Have a "great deal of confidence" in...	73	74	75	76	78	80	32	84
Medicine.....	54	60	50	54	46	52	46	52
Scientific community	37	45	38	43	36	41	38	47
Education.....	37	49	31	37	28	30	33	29
Organized religion..	35	44	24	30	31	35	32	32
Military.....	32	40	35	39	29	28	31	37
Major companies.....	29	31	19	22	22	27	23	32
Press.....	23	26	24	28	20	22	18	17
Television.....	19	23	18	19	14	16	14	13
Organized labor.....	15	18	10	12	11	15	12	9
Executive branch....	29	14	13	13	12	12	19	19
Congress.....	23	17	13	14	13	9	13	13
Supreme court.....	31	33	31	35	28	25	30	35
N =	1504	1484	1490	1499	1532	1468	1506	943

"I am going to name some institutions in this country. As far as the people running these institutions are concerned, would you say you have a great deal of confidence, only some confidence, or hardly any confidence at all in them?"

SOURCE: James A. Davis, Tom W. Smith, General Social Surveys Cumulative File, 1972-1984, (Ann Arbor: Inter-university Consortium for Political and Social Research, 1984), p. 152.

PUBLIC ATTITUDES CONCERNING THE REGULATION OF RESEARCH

Having examined the attitudinal environment for science in the United States, it is appropriate to turn to an examination of public attitudes toward the regulation of scientific research. As a starting point, it is necessary to recall that only about one in four Americans have firm attitudes toward science at all, and not all of those will have considered the issues surrounding the regulation of scientific research.

Perhaps reflecting the temper of the times, the 1957 study and other studies that followed it in the 1960's and early 1970's did not focus on the issue of the regulation of scientific research. Those early studies did provide important data about the environment in which science would function, but the issues involving the regulation of research were never sufficiently concrete or crystallized into a single controversy or incident to give shape to the issue.

In 1979, Miller and Prewitt initiated a series of questions asking respondents about various kinds of scientific studies and inquiring whether scientists should be "allowed" to conduct those studies. The structure of those questions implied regulation and they have been interpreted as a measure of the public's willingness to restrain scientific inquiry (Miller, Prewitt, Pearson, 1980; Miller, 1982, 1983a). A similar set of items were used in 1985.

The results indicate that about 40 per cent of the public would prohibit research dealing with the creation of new life forms of plant and animal life (see Table 11). In contrast, about a third of the population expressed opposition to studies that would involve weather modification or pain and suffering to animals. A quarter of the public indicated reservations about research to extend the average life span substantially.

The attentive public was significantly less likely to want to restrain scientific inquiry than were other citizens. Looking at the same 1979 and 1985 items, the proportion of the attentive public willing to restrain scientific inquiry was lower than the proportion for other citizens in every case (see Table 12). In 1979, a majority of the attentive public was willing to prohibit research leading to the creation of "new life forms," but by 1985, only a third of the attentive public was willing to prohibit research that would lead to "new forms of plant and animal life."

Other evidence suggests that most Americans think that scientific research is adequately regulated at the present time. In a 1985 study, a national sample of adults was asked to think about the level of governmental regulation in each of several areas and to indicate whether they thought that the current level of regulation was too high, too low, or about right.

TABLE 11

Public Willingness to Restrain Scientific Inquiry: 1979-85

Percent willing to prohibit the following types of scientific inquiry:	1979	1985
studies that might enable most people in society to live to be a 100 or more.	29%	25%
studies that cause pain or injury to animals like dogs or chimpanzees, but which produce new information about human disease or health problems.	NA	29
studies that might allow scientists to create new forms of life.	65	NA
studies that could allow scientists to create new forms of plant and animal life.	NA	41
studies that might lead to precise weather control and modification.	28	34
studies that might discover intelligent beings in outer space.	36	27
N =	1635	1992

"In terms of some specific kinds of research, do you think that scientists should or should not be allowed to conduct: ... ?"

When asked about the level of regulation of "basic scientific research," 57 per cent of the adults in the study indicated that the present level of regulation is "about right" (see Table 13). Eleven per cent thought it was too high and

TABLE 12

Public Willingness to Restrain Scientific Research, by Attentiveness: 1979-85

Percent willing to prohibit the following types of scientific inquiry:	Year	Attentive Public	Other Citizens
studies that might enable most people in society to live to be 100 or more.	1979	21%	31%
	1983	22	35
	1985	14	28
studies that cause pain or injury to animals like dogs or chimpanzees, but which produce new information about human disease or health problems.	1985	24	30
studies that might allow scientists to create new forms of life.	1979	52	68
studies that could allow scientists to create new forms of plant and animal life.	1983	19	43
	1985	33	43
studies that might lead to precise weather control and modification.	1979	18	30
	1985	27	36
studies that might discover intelligent beings in outer space.	1979	18	40
	1983	18	46
	1985	16	30
N (1979) =		307	1328
N (1983) =		398	1232
N (1985) =		447	1545

"In terms of some specific kinds of research, do you think that scientists should or should not be allowed to conduct: ... ?"

17 per cent thought that it was too low. Fifteen per cent admitted that they did not know enough about the regulation of scientific research to make a judgment. While it is reasonable to expect that somewhat more than 15 per cent of the adult population does not have a sufficient understanding of current regulatory policy to make a reasoned judgment, these results do indicate that there is not a strong public sentiment for a major change in policy in this area.

TABLE 13

Public Evaluation of the Level of Governmental Regulation: 1985

	Level of regulation is ...			
	too low	about right	too high	don't know
the conduct of basic scientific research	17%	57%	11%	15%
the use of chemical additives in food	40	27	28	6
the construction of nuclear power plants	31	34	28	7
the development of new pharmaceutical products	21	56	16	7
the conduct of genetic engineering research	21	43	15	21

N = 1992

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In contrast to the public's perception of the regulation of basic scientific research, the same 1985 study found substantially more public support for changes in the level of regulation of several technologies. For example, 40 per cent of American adults expressed the view the the present level of regulation of chemical additives in food is "too low" and 31 per cent indicated that they felt that the construction of nuclear power plants was inadequately regulated. Although a majority of American adults view the current regulation of the development of new drugs as about right, one in five adults characterize current regulations as too low.

Given the public's expressing willingness to "not allow" the creation of new forms of plant and animal life, the question concerning the level of regulation of genetic engineering research is of special interest. The results of the 1985 study indicate that 43 per cent of American adults support the present level of government regulation of genetic engineering research and that only one in five adults think that present rDNA regulations are inagequate (see Table 13). These results appear inconsistent with the previously described willingness to restrain research in this area.

One approach to this problem is to turn to utilize the differentiation between the attentive public for science and technology policy and other citizens. An examination of the evaluation of the current regulation of genetic engineering research by attentives and other citizens found that citizens

who were attentive to science issues were slightly more likely to see current regulations as too low, but the modal portion of both groups still viewed the present policy as about right (see Table 14). While the number of respondents who did not understand the issue was higher among non-attentives, the differential was not sufficient to explain the overall pattern.

In a very important way, these data illustrate the problem of trying to describe and assess the public's attitudes toward the regulation of science and technology. Science and technology, as I noted in the beginning of this presentation, are not salient issues to most Americans. An issue like genetic engineering may not be salient to many citizens who are in fact attentive to other facets of science. At the most basic level, it is doubtful that few American adults know what the present level of governmental regulation is in regard to rDNA research, thus it is difficult for them to assess the adequacy of present policies.

Nevertheless, when confronted by those issues -- by a survey interviewer or the evening television news -- many would and do form some preliminary reaction or attitude. Looking at these data, it is likely that the responses to the questions concerning whether scientists should be "allowed" to conduct certain kinds of research reflected a level of concern about research activity in that area. It would appear that a negative response did not mean that no research should be conducted in that area, but rather that it should be regulated or

scrutinized by the government. Since there have been no major accidents or disasters to date involving a genetically engineered microbe, many citizens apparently concluded that the present level of regulation must be working.

TABLE 14

Evaluation of Regulation, by Attentiveness: 1985

	Level of Regulation	Attentive Public	Other Citizens
the conduct of basic scientific research	too low	21%	16%
	too high	11	11
the use of chemical additives in food*	too low	46	38
	too high	23	29
the construction of nuclear power plants	too low	35	29
	too high	26	29
the development of new pharmaceutical products	too low	24	20
	too high	17	16
the conduct of genetic engineering research	too low	27	20
	too high	12	15
N =		447	1545

If the previously expressed willingness to restrain had meant an absolute prohibit or even a severe restriction, it is likely that the responses to the level of regulation question would have reflected a stronger sense of discontent. Consider the case of chemical food additives. In recent years, there has been a substantial volume of news and public discussion about the health and safety effects of numerous food addi-

tives. The data from the 1985 study suggests that the public has developed a strong sense that something is wrong in this area, and thus 40 per cent of the adult population expressed a preference for increased regulation in this area. In a similar vien, the continuing debates over the safety of nuclear power plants has stimulated in a segment of the population a clear sense that something else needs to be done in this area, as reflected in the 31 per cent of the adults population that favors increased regulation in this area.

Following this general interpretation, then, the results concerning the level of regulation of basic scientific research indicate a general acceptance of present policy. Sixty per cent of the attentive public for science policy expressed confidence in the present level of regulation of basic scientific research, as did 56 per cent of other citizens (see Table 14). It is clear that there is no grass roots pressure for a major modification in the regulation of scientific research.

LEADERSHIP ATTITUDES TOWARD THE REGULATION OF RESEARCH

At this point, it is necessary to return to the original discussion of the formulation of science policy in the United States. It was argued that the stratified model of specialized policy formulation was an appropriate description of the present procedures used in setting science policy. The conditions mandating some level of specialization were described.

Within this model of policy formulation, what would be the role or impact of the attitudes that have just been described? Does the apparent receptivity to the government regulation of science mean that there is strong public support for actions of this type? The model suggested that most policy would be negotiated between the decision-makers and science policy leaders. The attentive public is likely to become involved only when there is a dispute among science policy leaders themselves and between those leaders and the decision-makers. Citizens who do not follow science policy issues would likely be involved only in instances of direct referenda.

In view of the dynamics of the model just described, it is appropriate to ask whether there is any available evidence concerning the attitudes of science policy leaders on the regulation of scientific research. Do science policy leaders share a common view on the regulation of research, or is there

the kind of division that would lead to competition for the support of the attentive public for science policy? The only two systematic studies of the attitudes of science policy leaders have been conducted by Miller and Prewitt (1982) and Miller (1985).

Working with grant support from the National Science Foundation, Miller and Prewitt selected a sample of science policy leaders in the fall of 1981 and conducted almost 300 telephone interviews on a wide range of science policy issues. In the fall of 1984, Miller conducted a second study of science policy leaders, re-interviewing all of the leaders included in the 1981 study and adding a new national sample of almost 400 additional science policy leaders. The 1983 work was sponsored by an award from Monsanto.

In both the 1981 and the 1934 studies, science policy leaders were defined to be those persons who had done one or more of the following activities within the preceding two years:

(1) were officers of national professional or scientific societies or associations;

(2) had testified before a committee of the Congress on a scientific or technological issue within the previous two years;

(3) had served on a major executive branch science or technology policy advisory committee within the previous two years;

(4) had published a book or refereed a journal article on a science or technology policy matter within the previous two years;

(5) were members of the National Academy of Sciences, the National Academy of Engineering, or the Institute of Medical

Sciences;

(6) had won a Nobel Prize in a scientific field or a Field Medal (mathematics);

(7) had served as officers or on the board of directors of one of the 20 top science or engineering corporations on the Fortune 500 list; or

(8) were full-time science journalists for a national distribution broadcast or print organization.

An individual's name was entered into the universe list once for each time that he or she qualified; thus some individuals were entered into the universe list several times while others were entered only once. This procedure provided a weighting of the degree of leadership activity. The application of these criteria produced a total universe list of approximately 9800 entries, representing about 3500 individuals.

An examination of the demographic characteristics of the 630 science policy leaders included in the 1984 study indicates that approximately three-quarters of this group have an earned doctorate and that 88 per cent are male (see Table 15). Four in ten of the leaders were 55 years of age or older. Science policy leaders from universities were significantly more likely to have an earned doctorate than other leaders, but at least half of the science policy leaders from industry also had an earned doctorate.

Looking at the distribution of disciplines among science policy leaders, the data indicates that physical scientists are the most numerous, followed by engineers and physicians.

TABLE 15

Demographic Characteristics

	Earned Doctorate	Age 55+	Male	N
Science Policy Leaders	78%	44%	88%	630
Discipline				
Biological Sciences	90	39	79	101
Physical Sciences	89	50	93	180
Social Sciences	79	36	84	109
Engineer-Professional	68	51	95	145
Other	61	35	81	88
Employer				
For-profit	50	53	94	117
University	97	44	88	323
Other non-profit	67	32	83	155

Slightly over half of the science policy leaders in the United States are employed in universities.

In terms of the regulation of scientific research, 65 per of science policy leaders find the present level of governmental regulation of basic scientific research to be satisfactory (see Table 16). Twenty per cent of the leadership group felt that the present level of regulation is too high, and 11 per cent would like to see it higher. There was no significant differences from this pattern by either discipline or type of employer. While there is some division of leadership attitudes on this subject, the strong majority associated with the approval of the status quo suggests that there is not the kind of deep division that could lead to the direct involvement of the attentive public.

TABLE 16

Evaluation of the Regulation of Basic Scientific Research

	too high	about right	too low	N
Science Policy Leaders	20%	65%	11%	630
Discipline				
Biological Sciences	19	71	7	101
Physical Sciences	16	73	8	180
Social Sciences	21	66	8	109
Engineer-Professional	19	56	19	145
Other	25	60	11	88
Employer				
For-profit	21	62	9	117
University	22	64	11	323
Other non-profit	14	70	12	155

"Is the present level of governmental regulation of the conduct of basic scientific research too high, too low, or about right?"

It is also possible to look at the stability of leadership attitudes on this subject. The 1984 study included 215 science policy leaders who had been interviewed in 1981 and had been asked the identical question on the level of regulation of basic scientific research. The results show that there was some change in the attitudes of individual leaders over the three year period between the two interviews, but that the overall distribution did not change significantly. There was a slight tendency for leaders to gravitate toward acceptance of the status quo.

TABLE 17

Attitude Change Among Science Policy Leaders Concerning the Basic Scientific Research: 1982-85

1981-82 response	1984-85 Response: Too low	About right	Too high	Don't know
Too low	1%	2%	---	---
About right	5	43	14	1
Too high	1	18	8	1
Don't know	1	3	1	1

N = 215

Note: Percentages sum to 100 for total table.

"Is the present level of governmental regulation of the conduct of basic scientific research too high, too low, or about right?"

Beyond these leadership attitudes toward basic scientific research, it is also possible to examine leadership attitudes toward the regulation of two other different but related kinds of research. The 1984-85 leadership study asked leaders to assess the level of governmental regulation of "recombinant DNA research or genetic engineering experiments" and the "development of new pharmaceutical products." These are both timely and relevant subjects.

Recombinant DNA research reflects both very basic scientific work seeking to understand the fundamental organization of organisms, and work with short-term direct applications in

regard to plants, animals, and humans. It illustrates the thin line between basic and applied research. The results of the leadership interviews in 1984-85 indicated that two-thirds of science policy leaders supported the present level of governmental regulation of recombinant DNA or genetic engineering research (see Table 18). This basic pattern of support held across disciplinary and organizational groups.

Turning again to the 215 science policy leaders in both the 1981-82 study and the 1984-85 study, the data show some movement toward consensus in the attitudes of the leadership group during the last four years. Of the 20 per cent of science policy leaders who thought the level of government regulation of genetic engineering to be too high in 1981-82, half now believe the level to be "about right" (see Table 19). Of the 11 per cent who thought the level to be too low in 1981-82, five per cent now think the level to be appropriate. In the aggregate, the level of support for the present level of government regulation of recombinant DNA research increased from 56 per cent in 1981-82 to 67 per cent in 1984-85.

The 1984-85 study also measured leadership attitudes on an area of potential regulatory controversy -- the regulation of field tests of genetically engineered micobes. After a brief statement of positions in favor of and opposed to field tests of genetically-engineered microbes, each leader was asked whether he or she would allow or prohibit that kind of work. Overall, 84 per cent of science policy leaders indicated that they would allow field tests of genetically-engineered

TABLE 18

Evaluation of the Regulation of Recombinant DNA Research: 1985

	too high	about right	too low	N
Science Policy Leaders	9%	69%	13%	630
Discipline				
Biological Sciences	16	70	13	101
Physical Sciences	6	75	9	180
Social Sciences	7	74	11	109
Engineer-Professional	9	66	15	145
Other	14	58	18	88
Employer				
For-profit	9	61	15	117
University	11	74	9	323
Other non-profit	5	68	19	155

"Is the present level of governmental regulation of recombinant DNA or genetic engineering experiments too high, too low, or about right?"

TABLE 19

Attitude Change Among Science Policy Leaders Concerning the Regulation of RDNA: 1982-85

1981-82 response	1984-85 Response: Too low	About right	Too high	Don't know
Too low	4%	5%	1%	1%
About right	3	44	4	5
Too high	2	10	7	1
Don't know	3	8	1	3

N = 215

Note: Percentages sum to 100 for total table.

"Is the present level of governmental regulation of recombinant DNA or genetic engineering experiments too high, too low, or about right?"

microbes, and only 10 per cent were willing to prohibit this kind of research (see Table 20). Among science policy leaders trained in the biological sciences and in engineering, 89 per cent were willing to allow field tests of genetically-engineered materials.

In short, science policy leaders expressed a high level of confidence in the present level of government regulation of recombinant DNA research and there is no evidence of leadership interest in or support for a major increase or decrease in regulation in this area. This is an interesting result in view of both the intense controversies in two communities over

TABLE 20

Attitude toward Field Tests of Genetically-engineered Microbes: 1985

	Allow	Prohibit	Not sure	N
Science Policy Leaders	84%	10%	6%	630
Discipline				
Biological Sciences	89	7	4	101
Physical Sciences	83	8	8	180
Social Sciences	79	15	7	109
Engineer-Professional	89	7	4	145
Other	80	26	5	88
Employer				
For-profit	86	9	5	117
University	85	11	5	323
Other non-profit	85	8	7	155

"Some observers have expressed concern about the introduction of genetically-engineered micro-organisms into the environment, arguing that we cannot know all of the possible ecological effects. Other observers have argued that while caution must be exercised in the introduction of genetically-engineered microbes into the environment, the potential for substantial gains in food production and improved medical applications justifies any risks involved in field tests. In your own opinion, should field tests of genetically-engineered microbes be allowed or prohibited?"

the location of a P-3 facility in their area and the interest of many scientific leaders in the period immediately after the Asilomar Conference on recombinant DNA research. It would appear that the leadership of the scientific community become aware of a potential problem, that a system of monitoring and peer regulation emerge, and that there is a high level of satisfaction with this arrangement.

A similar pattern of leadership attitudes was found in regard to the level of regulation of the development of new pharmaceutical products. By 1984-85, two-thirds of science policy leaders expressed support for the current level of governmental regulation of the development of new pharmaceutical products. With the exception of science policy leaders trained in the social sciences, who favored higher levels of regulation, there was broad consensus on this view across disciplines and organizations (see Table 21).

TABLE 21

Evaluation of Regulation of New Pharmaceutical Products: 1985

	too high	about right	too low	N
Science Policy Leaders	20%	65%	12%	630
Discipline				
Biological Sciences	21	63	11	101
Physical Sciences	21	69	8	180
Social Sciences	17	58	24	109
Engineer-Professional	23	65	9	145
Other	17	66	14	88
Employer				
For-profit	34	56	7	117
University	16	67	13	323
Other non-profit	14	68	17	155

"Is the present level of governmental regulation of the development of new pharmaceutical products too high, too low, or about right?"

An examination of the change in attitudes among the 215 science policy leaders interviewed in both studies indicated that there was a movement toward consensus on the present level of regulation. Of the six per cent of science policy leaders who thought that the level of regulation of the development of new pharmaceutical products was too low in 1981-82, half had moved to the "about right" position by 1984-85 (see Table 22). Of the 39 per cent who thought that this regulation was too high in 1981-82, half had changed their position by 1984-85, primarily toward the acceptance of the status quo. Even five of the seven per cent who were unsure in 1981-82 had concluded that the level of regulation was about right by 1984-85.

The attitudes of science policy leaders toward the regulation of research and development activities in these two areas are important indicators of a general leadership view of the regulation of scientific research. Both areas involve work that can have direct health effects and one also involves basic research. The issue of the regulation of the development and testing of new pharmaceutical products in the United States has a long legislative history and is often cited as a case study in the conflict between the desire of the public for a high level of safety and the industry need for economic competiveness in international markets. Science policy leaders appear to have taken the middle road, accepting the present level of regulation and seeking to make it work effective-

TABLE 22

Attitude Change Among Science Policy Leaders Concerning the Regulation of New Pharmaceutical Products: 1982-85

1981-82 response	1984-85 Response: Too low	About right	Too high	Don't know
Too low	3%	3%	---	---
About right	6	39	5	1
Too high	5	14	19	1
Don't know	1	5	---	1

N = 215

Note: Percentages sum to 100 for total table.

"Is the present level of governmental regulation of the development of new pharmaceutical products too high, too low, or about right?"

ly. Science policy leaders appear to be more pragmatic than ideological in matters of regulation.

IMPLICATIONS FOR PUBLIC POLICY

In summary, these results indicate that there is a high degree of consensus among science policy leaders accepting the present level of government involvement in scientific research. Two-thirds of science policy leaders support present regulatory policies toward basic scientific research. Over the last three years, individuals have moved from one position to another, but a strong consensus in support of the status quo remained throughout this period. It is unlikely that an initiative for a major change in the level of regulation of scientific research will emerge from science policy leaders in the foreseeable future.

The attitudes of science policy leaders are reflected in the attitudes of the attentive public for science policy. Both the attentive public and the general public hold science and technology in high regard, appreciate the quality of life improvements from science and technology, and hold ever higher expectations for the future. At present, and for the foreseeable future, there is broad leadership and public satisfaction with the current regulation of basic scientific research in the United States.

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Appendix A

SOURCES OF SECONDARY DATA

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The following data sources were utilized in secondary analyses in the preceding report.

The 1957 National Association of Science Writers study was based on personal in-home interviews with a national probability sample of 1919 Americans. The interviews were conducted by the Survey Research Center at the University of Michigan. The field work for this survey was completed just prior (about two weeks) to the launch of Sputnik I by the Soviet Union and is the last measurement of American attitudes toward science and technology prior to the Space Age. For a full description of the study and results, see Davis (1958).

The 1979 survey of public attitudes toward science and technology was based on personal in-home interviews of a national probability sample of 1635 adults. Sponsored by the National Science Foundation (C-SRS78-16839), the field work was conducted by the Institute for Survey Research at Temple University. For a description of the design and results of the study, see Miller, Prewitt, and Pearson (1980).

The 1981 survey of public attitudes toward science and technology was based on telephone interviews with a national probability sample of 3195 adults. The study was sponsored by a grant from the National Science Foundation (NSF 8105662) and was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the sample and results, see Miller (1982).

The 1983 survey of public attitudes toward science and scientists was based on telephone interviews with a national probability sample of 1630 adults. Sponsored by the Annenberg School of Communications at the University of Pennsylvania, the survey was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the design and results of the study, see Miller (1983c).

The 1985 data on attentiveness to science policy were taken from a telephone survey of a national probability sample of 1992 adults. The study was sponsored by a grant from the National Science Foundation (SRS85-) and conducted by the Public Opinion Laboratory at Northern Illinois University. A technical report on this study will be released by the Public Opinion Laboratory in the summer of 1986.

The 1981-82 study of the attitudes of science policy leaders was based on telephone interviews with a national sample of 282 individuals. Sponsored by a grant from the National Science Foundation (NSF 8105662), the survey was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the study design and the methods used to identify and sample science policy leaders, see Miller and Prewitt (1982) and Miller (1983a).

The 1984-85 study of the attitudes of science policy leaders was based on telephone interviews with a national sample of 630 individuals. Sponsored by an award from Monsanto, the survey was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the study design and the methods employed to identify and sample leaders, see Miller (1985).

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DISCUSSION

Mr. FUQUA. Thank you very much, Professor Miller.

In your studies in looking back to the last 15 or 20 years, how would you view the research regulation developments in this country, and particularly, has the scientific community done a good job regulating itself, and how is that perceived? Or did you have a chance in your studies to examine questions of that type?

Dr. MILLER. I think that in regard to the first part of the question, about how has the peer review and the community control system worked, I think it has worked reasonably well. There have been a few failures here and there, but I think on balance that the contract, so to speak, that emerged from Mr. Bush and his colleagues at the end of the Second World War essentially where the Federal Government began to provide, continued to provide large-scale financial help to universities and to basic researchers with a minimum of direct control has probably been more responsible for the economic growth of this country and to our position, current position, in science and technology in the world than probably any other single thing that happened.

If you look, by contrast, to the period just before the Second World War, there are some amazing stories that come from that period of time because at that time the Federal Government did not have a grant procedure as we have now where you can provide funds for basic research and essentially allow the researchers to move forward; and even at the time that Professor Einstein had written the letter to President Roosevelt asking for help, by today's terms it seems amazing the total amount of help that was really requested was about $5,000. You probably do not see very many grant requests today for $5,000. And, in fact, what happened in the end was that, I think it was, the Bureau of Standards offered the $5,000 but there was enough redtape with it that the scientists involved turned it down and took the money from the Carnegie Endowment.

Most basic researchers preferred not to take Federal money because of the regulation and particularly the Navy procurement procedures, and that sort of thing. I think if we had not had a change of attitude that was set forth in the "Endless Frontier" kind of logic we would not have had the enormous growth in university research we have experienced.

In regard to the public attitude toward that, I think that the public tends to read the bottom line on these matters, and I think the public feels that, particularly in areas like health care where they can see directly, coronary care units, intensive care units and they see things happening that they knew did not happen for their parents, I think that there is a broad feeling that the system has worked. I would not want to suggest to you I think most people understand how it works. I think they do not understand how it works, but they have an appreciation of the fact that it has worked.

Mr. FUQUA. That is kind of like how laws are made. You probably appreciate them better if you do not see them in the making.

Dr. MILLER. That may well be the case. But I think on balance—I am sure you and this committee and Members of the Congress do

hear complaints from the scientific community about this regulation or that regulation—I think on balance, when you do what we have been doing, which is to survey a sample of people who meet various criteria for scientific leadership positions, there is a broad feeling we have arrived at a pretty healthy balance. That is not to say everything is perfect. But it is to say, in general, the balance is reasonably healthy, and I think the leadership group feels that, the group that is knowledgeable, and the public feels that. And I think that the broader general public which does not really follow the matter simply reads the bottom line and says, "Yes, we have better technology, we have better automobiles, we have better medical care, we have better communications, better transportation; something must be working right."

Mr. FUQUA. I was particularly thinking of things, and I guess my example is in the Federal field and others, such as the recombinant DNA research which is a self-regulated field, and the implants of the artificial hearts, and I would say to some extent the self-regulation of medical devices that would be designed to go in the body, that they meet certain standards and not break, were some certain quality of standard. If you get into dentistry or certain types of things—our colleague, Mr. Packard, is a dentist—but certain things that are implanted in the field of dentistry or other fields where there tends to be a self-regulation, do you find that the public is satisfied with that?

Dr. MILLER. I would say probably most of the public if you asked would say those things in fact are regulated somewhere, somehow. You could not sell a fraudulent device.

Mr. FUQUA. They have confidence in the system.

Dr. MILLER. Yes. They would think somehow there must be someone checking that. This is a broad sense that there is a network of regulation that if a person—one of the difficulties in some of the medical fraud cases is people tend to take the view that if you can advertise it and if it appears anywhere, it must be OK because otherwise surely people would not let you do that. This is a kind of commonsense notion that people would not allow fraudulent devices to be sold or bad products on the market. I think there may be a little misunderstanding in that the sense that there is a perception that someone probably is watching out for that and, as you know, it is not always as tight. Some of it is not Federal regulation; some is State regulation on the sales.

Mr. FUQUA. We have—and I do not want the impression to be left that there is no regulation. We have the Food and Drug Administration that regulates a lot of these things. Is there overregulation, let's say, with the Food and Drug Administration and their procedures about the efficacy of drugs before they get to the market? Sometimes there is a very long period of time between the development of the drugs and before they are approved for sale, and it differs in different countries of the world.

Dr. MILLER. Right. If you look at the public attitudes toward drug regulation and drug safety, it goes in cycles, depending on when you had your last accident. If you have a thalidomide problem, there comes a period of time when the public is very wary of these things and they are very supportive of more regulation. The last two or three measurements we have made of national samples sug-

gested that an increased proportion of people say the regulation of the development of new pharmaceuticals is about right. There seems to be a certain comfort level with it now. I would add, however, that without question if next week we had a drug that was another thalidomide type of problem, a drug that reached the market that had an undesirable side effect, a particularly catastrophic one, there would be a pendulum swing and say we ought to watch it.

The assumption is the system is working and someone is watching it; and until something convinces the public to the contrary, there is a sense, I think, that things are being adequately watched and if they find something getting through the net and you have a thalidomide type of problem, then, as it must be, you have regulation again.

I think for the last 10 years or so in terms of data, there is kind of a gradual decreasing of concern about drug regulation and a period of acceptance, but during that period of time there have been no major difficulties of that kind, and the public attitudes are very sensitive to that kind of thing. If you get headlines for the next month about deformed babies, then, of course, it will swing right back up again.

Mr. FUQUA. Do those attitudes change according to demographics: age, sex, education level, rural versus urban, varying types of groupings that you could have?

Dr. MILLER. Well, yes.

Mr. FUQUA. On the question of regulation?

Dr. MILLER. I think in terms of—there are two sides to that coin. One is the expectations of science that I alluded to before. That really cuts across almost all demographic groups without differentiation. There is a broad feeling in our society that the solution to most things can be done or improved or helped by science and technology.

In terms of the sense of regulation, that is really limited, as I suggested to the attentive public and to that one in four adults who are, in fact, following science and technology at some level, and, as I said before, there is not a sense of discontent now at all. There has not been any reason for discontent in the last several years. There has not been the kind of bad newspaper that causes discontent, and I think there is a general satisfaction, a general expectation that the system is somehow functioning reasonably well in that regard.

In terms of the issue about basic research, probably even a smaller segment of the public really appreciates what regulation is involved there because, as a number of people have pointed out over the years, most of the American people never see science. They see it on *Nova*, but they do not see it very often. We encounter technology when we buy a pharmaceutical, or we do this, or we turn our computer on, or turn on our television and it works. We say that is nice. What goes into building a chip or what goes into figuring out the physics of that chip is really not something people even think about very often, so there is not really—you cannot do just a mass survey and say what do you think about it because most people have never really thought. There is not a standing attitude out there in that sense on issues like basic scientific research. You

have to refer to the leadership groups, and to the attentive public, and that segment of the attentive public that seems to have an attitude toward that, and those are positive, I would say.

Mr. FUQUA. Once the people's attitudes have been formed, good or bad, how hard is it to change it to the other way? For instance, there is kind of a bad feeling in this country toward, say, nuclear power. We just had an accident of the space shuttle *Challenger*, where people saw on live television this horrible event. Yet, in the public opinion polls after that, there was still strong opinion we should continue our space endeavors. After Three Mile Island, there was a very great concern about nuclear power and, of course, that nuclear power may be associated with nuclear weapons and people do not distinguish between power generation and weapons. Do you find in certain sciences negative feelings?

Dr. MILLER. Those are two very different cases. Let me deal first with the nuclear power case. Nuclear power is an issue which divides the American people equally. There are almost as many people opposed as in favor of it. Part of the difficulty is that has been a very, in my view, truncated discussion in terms of trying to educate the public on that issue. There are groups who are working very diligently to try to put before the public pros and cons in a somewhat rational fashion. One of the arguments—and certainly when we talked to leadership groups, if you would ask what is probably the most powerful and most persuasive argument in favor of nuclear power, I think it is that the alternative is fossil fuels and we know the environmental consequences of fossil fuels. The irony of the situation is the people who ought to be making that case, namely, the utility companies, also are very big users of fossil fuels and, therefore, find themselves constrained to make that argument because they have vested interests in both camps. They would like to advance nuclear power which is, indeed, a technology that probably will continue to be used and probably an increasing proportion of our power supply, and the best argument for it, our best argument in favor of nuclear power, I think, has to do with the alternative fuel sources, that is, the health hazards, known health hazards that are associated with burning fossil fuels; and yet that argument is not made very much and I think that the public on the whole is very sensitive to health questions.

If you look back on the last 20 years at the environmental movement, you could make, I think, a persuasive case; but you would have to make it probably on the basis of health and environment. And I think that the issue in part is that argument has not been made well, because to make that argument strongly would create pressure on the way we produce the majority of the electric power today.

Mr. PACKARD. Will the chairman yield?

Mr. FUQUA. I was going to yield to you.

Mr. PACKARD. Let me pursue this for a moment. I have a meeting in a few minutes. But do you not feel that the nuclear issue, the nuclear power issue has become an economic issue to a large extent and that the companies, the utility companies have backed away from pushing for nuclear power because they have gotten burned so many times on the commission of it? Where it was perceived initially to be a cheaper form of power and energy, it has

become one of the more expensive in terms of final product, and they simply have chosen not to try to buck any longer some of the pressure groups that have driven up the costs in terms of delays, regulatory increases and the problems of keeping operating. I have talked to enough in my area—I have a nuclear plant in my district—that they say they are not going to touch it again for another at least 15 years, simply because what was projected to be a half a billion dollar plant turned out to be a $2 billion plant and where they were projecting to put out power that would be 5 cents a kilowatt, or 5 mils, it turned out to be 10 times that amount and now it is not competitive. They simply backed away because of the economics. What is your response?

Dr. MILLER. I think in terms of the leadership of the industry that the economics are very important, and I think even more probably than the price per kilowatt is, given some of the other difficulties with plant financing, the financial community probably is even more reticent than ever to put up the billions of dollars to build new plants. Even if the companies were inclined, where you would find the investment capital for major investments would also be questionable, but I think the public does not understand that. I think that is an issue that is understood by leadership groups and certainly the leadership group of the utility companies, but I do not think there is a broad feeling in the public that nuclear power is terribly more expensive yet. As new plants are factored into the local rate structure, that may become something the public begins to sense and feel; but I would say at the present time if you asked people across the country most people would feel nuclear power is still cost effective. The typical consumer does not see that issue yet. I think the utility executives and the financial community do see it and some of the science community will see it.

Mr. PACKARD. What we are going to see in the industrial community because of the competition is now at the same time that our utilities are not building powerplants anymore, nuclear powerplants anymore, we find as we travel to places like Japan and France and other countries that they are building them at greatly—they have really tripled their emphasis on them to the point where 30, 40, 50 percent of their energy is going to be produced by nuclear power within the next decade, and they are building them at a much cheaper cost than we are able to build them now, and the competition simply for the energy is going to be very difficult for our country to match.

Dr. MILLER. There are difficult economic issues because this country happens to have a large supply of relatively cheap coal. Therefore, in terms of economics of the marginal, if you need to create additional marginal power production, what is the cheapest way to get it in? In the short term, the cheapest way is coal. I think, in answer to the chairman's previous question, the issue in part may well be if you want to make the argument in favor of nuclear, it is not the economic argument—that was made two or three decades ago—but the best argument may be the environmental. On the whole, there are risks of operating a plant, but those risks are sporadic and fairly long odds compared to the very immediate and known risk of burning fossil fuels.

Mr. PACKARD. The question that the chairman asked, how do you change attitudes and does that take a longer period of time to change from a negative to a positive attitude than it does the reverse, changing from a positive to a negative attitude? Often we find where it can take place quickly with one serious incident. You can have a positive attitude just almost overnight become a negative and then the whole industry suffers. I am concerned.

We had a hearing yesterday on altered genetics, and there is a general perception right now with many Americans that any time a genetically altered microbe is released into the environment that it is like releasing the plague into the environment and they would like to see us totally stop all research in that area because you cannot contain it. I am concerned that perhaps maybe misinformation is dangerous in terms of preventing a great and emerging technology from really fulfilling its dream. Is that a problem that we struggle with in the nuclear industry?

Dr. MILLER. Well, I think that the process of changing attitudes is slow by any measure. They do not change very rapidly in any particular issue, even on the issue of nuclear power. If you look at the last 20 years, the changes have not been day and night changes. Even after Three Mile Island there was probably an adjustment of 5 or 6 percent in the aggregate public attitude. I think that those attitudes often, in my view, are formed earlier in life. I think the college years are the years, adult years, which are very important in the attitude formation, and people develop certain kinds of general perspectives on science broadly and certainly technology. I think it is possible to change attitudes. People do listen to information. They certainly yield to economic pressures.

A few years ago, I can recall attending a hearing where some of my colleagues were arguing that we would never be able to stem consumption of power, that the American mode of life was we would always consume more of everything. When gas got to be $2 a gallon, people bought a lot less of it, and I think there is some indication that you can change patterns. People bought smaller cars and so forth.

Mr. FUQUA. But they are going back.

Dr. MILLER. Gas is 90 cents now. Those things do have a behavior effect.

In terms of the recombinant DNA, that is a particularly interesting one and I have been working on that for some time. The difficulty is that 9 out of 10 people have not the foggiest what DNA is, let alone recombinant DNA, and most people, if you ask them the kind of questions—and we have done this accidentally a couple times. We have asked in 1979 if the public objected to scientific studies that led to the creation of new forms of life. Well, you know, two-thirds of the people objected to that. It appears that we are asking them Frankenstein questions. You want to clone people who have three heads or whatever. Then I asked them—we did this a couple years later—"Would you object to creation of new forms of plant and animal life?" And it drops down to about 20 points or so. If you ask a particular question like: "Would you like to have a manmade insulin?" Of course, everybody wants that. That happens also to be the same technology. Would you like to have a way of increasing milk production?

Mr. PACKARD. You ask the question: "Would you like to have a genetically-altered microbe released into the environment?" You get 95 percent of them who would say: "Goodness, no."

Dr. MILLER. It sounds like a science fiction kind of question. I think that really is central to the question the chairman posed before: "What should we be doing in some of these matters?" I think you need to provide the kind of basic science education to all citizens, so when an issue comes to the public agenda that you do not have to go back to the very beginning and say: "This is what a cell is." Because to some extent when you try to argue the question about recombinant DNA in this country you are back to the question of trying to explain to about 80 percent of the American public who does not know how cells function what a cell is and, therefore, then to the 90 percent who do not know what recombinant DNA is, you are trying to talk about whether it is safe to splice plasma. Then you are talking to 2 percent, and the problem with these matters is that it is very hard to go back and do that much basic education. You can do some, and there has been, I think, a lot of work that *Nova* and other people have done in trying to explain. *National Geographic* a couple years ago had an extraordinarily good piece on recombinant DNA that I think was comprehensible to every high school graduate in the world, and anyone who read that would have been able to see a process. They would not necessarily have immediately agreed with it, but they would have understood what we are talking about.

Those things do not come overnight. I think to the extent that we build a stronger science and mathematics base so every high school graduate would know what DNA is, and every high school graduate would know some of those things, then as these issues come to the public policy agenda they would understand them. There is no question over the next two decades, all of you who are making public policy are going to be facing more and more of those kinds of issues. The old black and white, right and wrong, moral, immoral, whatever kind of issues, you do not get very many of those anymore. Most of what you get is complex issues. How you deal with very complex topics, and to the extent you are going to deal with them, you need a public that can understand complexity; and I think the investments we make in this country in basic science and mathematics education should be for all citizens. We should push very hard to do that. Many States have been doing that. Many States are now requiring 2 full years of high school science and some States are requiring 3. That is a very refreshing change in my view. We have had for a long time in many States like Illinois a situation where until a year ago, I think, a person could graduate from many high schools in Illinois with 1 year of science, and not the named general science, but it was a very vague exposure to anything that could be called science. I think the effort of many States in response to the reports of the National Science Boards Commission, and the Bell Commission, and other people, have been positive in that regard, but I think that pressure needs to continue.

You know, the last time we did this was after Sputnik, because of the idea of Sputnik rotating over your head. There is a certain urgency about doing science and mathematics, but even then we

did not try it for all students. The thrust of the Sputnik program was, mainly, this country has got to produce more engineers that are as good as the Soviets are, and we made a big effort to improve advanced science and opportunities for the very best students; and even if you look back at that program, there was very little effort made in that time to include all students. It was really an effort to provide substantial opportunities for our best students and that has worked. We have produced them, as most people in the scientific community would argue without any real evidence to the contrary. People come to this country from everywhere to study science and technology. There is not a flow of American bachelor students to the Soviet Union or even to Japan. There is a good flow of Japanese students to American universities, but not the other way around. We do produce good scientists and engineers. We have the capability of doing good science and mathematics education, and for those people going into those professions I think we do an extraordinarily good job. What we do not do is the same quality of job for educating the people who are going to vote to pay for that science and mathematics and technology eventually.

Mr. FUQUA. In the field of regulation, if the administrative burden gets so high and costs so much, will it influence the type of research that people will do and they will——

Dr. MILLER. Yes, I think that——

Mr. FUQUA [continuing]. Decide to go somewhere else, and I am thinking specifically, say, something that involves animal research, and that has been a very controversial subject?

Dr. MILLER. Yes. I think that among the leadership groups there is a sense that there may have been some areas that were overregulated. I think among most social scientists, for example, there was a feeling some years ago when we first started doing human subjects regulation that every questionnaire anyone used for any purpose had to be approved by a committee, and I think that was an overreaction and it was burdensome. I chaired one of those committees at my university for several years, and I cannot recall we ever changed a question. People just had to go through that process; and I think when you require people to go through a ritual that is devoid of substance they lose some confidence in the process. People saw that as paperwork. I think, to some extent, some of the very extensive OMB clearances today are an example. Every time anybody in the Federal Government asks more than three or five questions, it requires a special clearance, and I think some of those things probably are kind of counterproductive. People, I think, oftentimes try to adapt their research to get around those; and if there is enough international cooperation in science, that some of the basic research will go offshore the way some of the pharmaceutical research did. I think if something becomes overbearing, that there are enough networks of people so if you cannot do it here you can do it at Oxford, or you can do it in France, or in Germany. And if those regulations were to become overbearing, I think you would see a migration of research to places where the regulations are not so stringent.

But I would say, you know, the animal regulations are just now emerging as a subject of controversy. There is a certain sentimental reaction on some people's part about it, although in the last

study we just finished for the National Science Board, we did ask people if they were willing to allow studies or support studies that caused pain and injury to animals if that process yielded knowledge about human health that would improve human health, and the answer was, "Yes," they were willing to do that.

Mr. FUQUA. What was the percentage or do you know?

Dr. MILLER. I would have to supply that, Mr. Chairman. I cannot tell you off the top of my head. It was over 50 percent. I cannot recall the exact percentage, but I will supply that to your staff.

Mr. FUQUA. How do we resolve the public's expectations for scientific progress and its application when we have an increasing trend of regulation? Is the public aware of the adverse effect regulation may have on scientific progress and leadership?

Dr. MILLER. No, I do not think the general public is aware of the level of regulation at all. I think there is a sense, as I suggested to you in regard to medical phenomena, that someone is watching these things. If you even ask them whether it would be the Federal Government or the State level or the local health departments, there would not be a clear distinction in people's mind about that. I think among the leadership groups there is a much greater awareness of regulation, and I think that some of the regulation that has been most resisted, I suppose, by practicing researchers has been really more general regulation, not ones aimed at science. I think the paperwork that comes out of just simply these environmental programs—environmental impact statements would not apply to basic scientific researchers, but all segments of the society kind of restraints, that initially caused a good deal of resistance. I think, in many cases, people have lived with that quite successfully, and at most of the universities, by and large, people simply learned there is a different way of doing recruitment, a different way of handling environmental concerns; and that if you are going to dispose of a chemical, you better think very carefully about where you are going to put it, and it is really your responsibility to think of that as opposed to some other unnamed entity who might—there is always an assumption in a sense among lab people that if you pour it down the drain someone somewhere must be watching it, and George never seems to get all those jobs done. And one of the impacts is, with some of the regulations, people had to stop and think: "Where does the stuff go, and what do you do with it, and how do you dispose of it?" I think, on the whole, that has been a learning process, but probably a valuable one, and I think there is a pretty broad acceptance. I do not sense any real major discontent about that.

Mr. FUQUA. That was my next question. Do you think we need to do a better job, whether it be through the education system or through public officials and others, in trying to not educate the public, but to make them aware of the importance of what scientific research is doing and that there is adequate regulation taking place, also the pitfalls of overregulation, or is it a pretty happy medium now?

Dr. MILLER. I think you have a pretty healthy balance now. I think the efforts that have emerged through the last decade of improved informal education for adults are important. When people go to the science museum today, they learn not only about what

scientists are doing, but increasingly, those exhibits teach people more about the process of science as opposed to magic box phenomena. I think the sense of regulation and deregulation is now in more flux in people's minds, not because I think of science, but because they have seen other cases of regulation and deregulation. They have seen the effects of airline deregulation. They are seeing the effect of telephone deregulation and so forth. And I think there are mixed feelings about that.

On the one hand, some deregulation apparently is yielding results, at least in the short term, or is viewed more favorably by the public and some viewed less favorably. And I think there is probably greater awareness that the impact of regulation does have some ultimate effect on the cost of products to you, and the availability of them, and the quality of them.

Mr. FUQUA. You are saying there really is a tradeoff between excessive regulation and total deregulation?

Dr. MILLER. Yes. I do not think the public wants total deregulation in very many areas. They expect there to be a safety net on matters. On the other hand, I do not think they would want things restrained so that you could not get a product on the market. I think there is an expectation the people who know what they are doing in these matters, as the public will see it, will strike that happy medium. I do not think you can rely on the public for guidance as to what the happy medium is. That requires people in the field, in the academic side and the industrial side, to have those kinds of debates to settle where that happy medium might come, but the public certainly expects and supports that kind of enough regulation to prevent harm but not enough to prevent progress.

Mr. FUQUA. We in this study are looking 20, 40 years into the future hopefully, and I am sure none of us have any idea of what the world is going to be like 40 years from now. But having to try to look that way, do you perceive from what we know today the need for any further regulation of science and technology?

Dr. MILLER. Yes, I think it is important in a democratic society for the public to have a sense of participation, in a sense, in what we do as a society in terms of science and technology. I think it is important that the public ought to have the power, if there is a technology or particularly a technology that is unacceptable, in some fashion the public ought to have the power to regulate that. It is much harder for me to envision how you can regulate basic science because it is in the minds of people who are doing it; and as we well know, in American science—if you take something like the Nazi regime, people who had certain ideas in their minds simply went to another country. Fortunately, most of them came to this country and helped greatly American science. So I think that in terms of trying to conceptualize how do you get scientists not to think about something like atomic energy, I do not know how you do that. I am not sure it is desirable and I am not sure it is practical.

In terms of technology there is indeed, an opportunity, I think, and a need for the public to feel some confidence that someone has looked to see what the consequences of a technology may be. I think the kind of philosophy that was embodied in the environmental impact statements was a good philosophy. People should say

what is going to happen to that technology 30, 40, 50 years down the road. There has been some very academic work in retrospective technology where people have gone back to technologies that were created at various times, and even simple technology that had enormous implications because people who did them did not think very far ahead, what happened when you made one change or the other in the water system or whatever.

So I think that, particularly in the regulation of technology, the public expects that. I think they expect reasonable regulation, but they certainly expect regulation.

Mr. FUQUA. Just for the sake of regulation?

Dr. MILLER. No. For safety. I think that people do not feel they can—and they correctly feel it—become competent and watchful of every technology. I mean if you put the burden on the consumer of making personal judgments about the efficacy of every product on the shelf, you would not have time to earn a living. It will be an enormous burden. I think the public expects someone is watching that. So I think when a technology hits the marketplace there is a sense that someone should have looked at it. That does not say—that is not to argue at all that you need to have repressive or overbearing regulations, but I think the public does expect a safety net in all areas of technology that reach consumers, and I think there is a sense that people have that the Government already does that. And, in the absence of major catastrophes, the sense is the Government does it reasonably well; and since we get remedial actions when we have a thalidomide, or you have a problem of some kind, or even a Three Mile Island, where people say temporarily that was a problem, someone should have been watching that more closely and you get a thermidor effect coming back the other way.

Mr. FUQUA. I think what you are saying is the more confidence the public has in what is being done in science, the better satisfied that they are. You still get into emotional subjects.

Dr. MILLER. Yes, you do.

Mr. FUQUA. Nuclear power is a very emotional subject; the use of animals in research among some people is a very, very emotional subject. The different ways of disposing of toxic waste, for instance, one issue that has evolved is that of burying it in the ocean. The alternative to that, I guess, is burying it on land. And there is an offset, but they are very emotional subjects and people feel very strongly about that.

Dr. MILLER. Yes, sir.

Mr. FUQUA. And, of course, science and technology, I think, is in and of itself very, very neutral depending on how you use it. Whether you use it for good or whether it is used for bad, sometimes it gets blamed for bad things. It is very easy to get in a car. You find the gadgets and you may not understand it, but you blame the manufacturer for something that is not working right and maybe it is not, or other electronic devices and so forth you may have, whether it be simple radio or TV or whatever it is.

Dr. MILLER. I think one of the phrases I used to find, and do not hear it as much as you did 10 years ago, but there was a period of time where every time something broke somebody would say: "Well, if you can put a man on the Moon why can't you fix my air-conditioner?" There was a sense in which with any piece of equip-

ment, you know, once we put a man on the Moon there was no excuse for any piece of equipment not working because clearly if you could do that you ought to be able to fix this other thing—whether it is your carburetor or air-conditioner, there is no excuse for it not working. And I think there is a sense in the public. They may not think of the man on the Moon, although that is now history to most people. If you can put up a shuttle or if you can do that, why can't these other things happen? There is a very high expectation that there is a technological solution to a large number of problems.

Some of those problems will be emotional, but I think on the whole the thing I would say to you and to your colleagues in the Congress is that to try to keep in mind that if you hear 200 or 300 very angry people, that may not represent the full—there is probably another 200 or 300 you could easily find on the other side. One of the things that I think is useful when you are reading public opinion data is to remember this: every percentage point in a national survey is 1.7 million adults. So when someone says it is only 5 percent, that is only 8½ million people. This is a very big country, so that sometimes you hear when a few people are angry about something, very jealous of protecting something, it is important to recognize that there are millions of people who do follow science. I think there is probably between 35 and 40 million adults who buy magazines, read reports, follow things. That is not 170 million, but it is certainly a pretty large market share considering how many people follow other kinds of issues. And I think that there is a public awareness out there, and I think if we continue to improve science education, if the marketplace continues to respond in terms of science magazine and television coverage and so forth, I think the quality of the public's knowledge will increase. But it is like all educational changes; it probably is more glacial in character than it is volcanic. People do not—we are not going to have in our lifetimes a situation where 80 or 90 percent of the American people are scientifically literate. That simply is not going to happen. But if we could increase it from 7 to 20, it would be a great step forward, I think.

Mr. FUQUA. One final question. When there are problems that develop in science and technology or whatever, do you think our reaction time is appropriate or we respond in a timely fashion?

Dr. MILLER. It really differs a lot from case to case. I think in the case of the shuttle accident recently, for example, I think the coverage of that and the kinds of discussion that have come out through the hearings and things that have gone on since then have been pretty good. I think the public has been able to follow and comprehend that and develop increasingly some attitudes toward that. I think, on the other hand——

Mr. FUQUA. Not that it is being swept under the rug.

Dr. MILLER. Yes. I think you always have to approach these things with great candor. I think what the public worries most about is closed doors. If you cannot let the public know, it must be awful, that sort of thing. I think the Three Mile Island was handled very badly. There were so many counterclaims, and one of the things that the public finds very confusing is that since they have what is almost an act of faith in regard to science—I have given a

lecture several times on faith in science—what we have in this country is a situation where large numbers of people believe science will cure cancer, desalinate water, whatever, but they do not understand how it happens and that essentially is what is called the faith system. And in a faith system you have to have some confidence in the priest. Then when you get two priests arguing, or you get two physicists arguing about nuclear power, or you had very poor spokesmen after Three Mile Island saying it was a manageable accident, and other people saying it was a catastrophe, I think that whole thing never reached any kind of closure, and it led to a much more confusing public mind set. I would say that was not handled well. I think the shuttle thing has been handled well. I think some of the other kind of smaller incidents have been handled pretty well.

The quality of science journalism in this country has improved a lot in the last two decades, and it is getting better, and more and more networks, and more and more large television stations now have full-time science reporters who are trained with some science in their background, and who cover topics often enough that when something does arise they have enough context, background knowledge to be able to present it to the public in a reasonable fashion. That still is not progressing as rapidly as I personally would have hoped it would have, but that is the kind of thing that makes informing the public easier, because when an emergency happens, you cannot go back and train experts. If you are going to have people in the media who are going to convey information to the public, they have to have the information preaccident or preevent or it is not going to be very effective, and I think that there is a growing number of people in the media who are competent and who understand enough about science and technology that when something like that happens very often they are able to put together a presentation that is balanced and that is reasonably accurate.

Mr. FUQUA. I want to thank you. I think I agree with you. I think the more the public is informed, the more openness we have, that the better the public understands and increases the confidence level in science and technology.

Thank you very much for being here.

Dr. MILLER. Thank you for inviting me.

[Whereupon, at 9:28 a.m. the task force adjourned, to reconvene on March 6, 1986.]

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SCIENCE AND THE REGULATORY ENVIRONMENT

THURSDAY, MARCH 6, 1986

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
TASK FORCE ON SCIENCE POLICY,
Washington, DC.

The task force met, pursuant to notice, at 8:30 a.m., in room 2318, Rayburn House Office Building, Hon. Don Fuqua (chairman of the task force) presiding.

Mr. FUQUA. We resume our hearings before the Science and Technology Science Policy Task Force on science and the regulatory environment. And we have two very distinguished witnesses this morning: Dr. Harlyn Halvorson, director of the Rosensteil Basic Medical Sciences Research Center at Brandeis University, and Dr. Edward J. Burger, director of the Institute for Health Policy Analysis at Georgetown University Medical Center.

Gentlemen, we're very pleased to have you this morning. And, Dr. Halvorson, if you will begin. We'll hear from both of you and then we'll open it up for questions.

[A biographical sketch of Dr. Halvorson and Dr. Goldberg follow:]

DR. HARLYN O. HALVORSON

Harlyn O. Halvorson born Minneapolis, Minn. May 17, 1925. Education B.S. Univ. of Minn. 1948, M.S. Biochem. Univ. of Minn. 1950, Ph.D. Bacteriology Univ. of Illinois 1952. Instr., Asst. Prof. U. of Mich. 1952–5, Merck Senior Postdoc. Fellow Inst. Pasteur, Paris 1955–6; Assoc.-Full Prof. Bacteriol., U. of Wisc. 1956–71. Prof. Mol. Biol. 1964–71, Chm. Mol. Biol. 1966–71; NIH Career Prof. 1963–71; Prof. Biol. and Director Rosenstiel Basic Medical Sciences Research Center, Brandeis Univ. 1971–. Visiting Investigator Lab of Enzymology, CNRS Gif-sur-Yvette 1965–6; Fogarty Senior Intl. Fellowship, Univ. of Edinburgh 1980. Concurrent membership NSF Adv. Panel Quartermaster Corp. 1958–64, NIH Fellowship Panel Biochem. and Nutrition 1961–4, Mycology and Microbiology 1964–69; Fogarty Int. Fellowship Rev. Panel 1972–4; Mycology Task Force 79, NIGMS Council 1984–; Natl. Res. Council, Space Science Board, Committee Planetary Biol. and Chem. Evolution, Adv. Comm. to USDA; Am. Cancer Soc. Adv. Panel; Bioscience Inf. Service, Member Board 1982–5, Chm. of Board 1986–; Foundation for Microbiology, Trustee 1972–, Treasurer 1983–; Council of Sci. Soc. Presidents Vice Chm. 1972–8, Chm. 1978–9; Research Animal Alliance, Member Exec. Comm. 1980–4; Natl. Down Syndrome Soc. Member Prof. Advisory Board, 1980–4; Marine Biol. Lab. Woods Hole, Trustee, Member of Exec. Comm., Investigator, Teacher Physiol. course; Instructor-in-charge Microbiol.; Am. Soc. Microbiol. Council Pol. Comm., Pres. 1976–7; Chm. Board of Public and Scientific Affairs 1979–; member Am. Soc. Microbiol., Am Chem. Soc., Am. Soc. Biol. Chemists, Am. Acad. Microbiol., Am. Soc. Cell Biol., Am Assoc. for Advancement of Science (fellow 1985), Am. Acad. of Arts and Sci. 1978. Research interests Induced enzyme synthesis, physiology and germination of aerobic spores, cell cycle in yeast, invertase secretion, polyphosphate metabolism, marine spore formers, heavy metal resistance.

DR. MICHAEL GOLDBERG

Education: B.S., Union College, Schenectady, New York, 1965; Ph.D., Yale University, New Haven, Connecticut, 1970.

Professional experience: Postdoctoral Fellow, Department of Biochemistry and Biophysics, University of California, San Francisco, 1970–75; Health Scientist Administrator, National Institute of General Medical Sciences, 1975–78; Senior Health Policy Analyst, Office of the Secretary, HHS, 1978–79; Executive Assistant to the Commissioner and Associate Commissioner for Policy Coordination, Food and Drug Administration, 1979–80; Branch Chief, Division of Legislative Analysis, NIH, 1980–81; Director, Division of Legislative Analysis, NIH, 1981–84; Associate Director for Program Planning and Evaluation, NIH, 1982–84; Executive Director, American Society for Microbiology, 1984-present.

Awards, Honors, professional societies: Phi Beta Kappa; Sigma Xi; American Chemical Society; Damon Runyon Postdoctoral Fellow; Gianini Foundation Postdoctoral Fellow; NIH Director's Award.

Personal information: Birthdate: March 18, 1944; Marital status; Married, one child; Home address: 7508 Hampden Lane, Bethesda, Maryland 20817.

STATEMENT OF DR. HARLYN O. HALVORSON, DIRECTOR, ROSENSTEIL BASIC MEDICAL SCIENCES RESEARCH CENTER, BRANDEIS UNIVERSITY, WALTHAM, MA, AND CHAIRMAN, PUBLIC AND SCIENTIFIC AFFAIRS BOARD, AMERICAN SOCIETY FOR MICROBIOLOGY; ACCOMPANIED BY DR. MICHAEL GOLDBERG, EXECUTIVE DIRECTOR OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, DC

Dr. HALVORSON. Thank you, Mr. Chairman. I very much appreciate the opportunity of coming and addressing what I—what many of us have watched and wanted for some time, a very long-ranged look at American science. I congratulate the committee for its efforts in delving into the very many problems.

I'm also very appreciative of the Office of Science and Technology Assessment study on "The Regulatory Environment for Science." I think that Dr. John Andelin and Dr. Harvey Brooks are to be congratulated for an excellent summary which brings out many of the issues that one would want to address.

Of the many topics of concern to us as individual scientists and as professional organizations, I'd like to address only three in the brief time this morning. The first of these has to do with the regulation of biotechnology research and development.

The roles that have been played in following the development of recombinant DNA research is an excellent model for its regulation that's been shown by the Recombinant DNA Advisory Committee for the National Institutes of Health. We have followed this for many years, and have been very pleased with the way that technology has been monitored, surveyed, and reviewed as well by the scientific community. We've been concerned for the last few years of how this same advice could be applied outside of the area of university research, and have followed with great interest the various efforts to try and apply this to the commercial sector.

We do have some concerns about the various efforts at the present time to try and review the laws that govern the commercial research in recombinant organisms, particularly those released to the environment. I think it's important that these should be viewed, and I hope that in the year ahead that the problems with both TSCA and FIFRA, as a mechanism for dealing with this, will be very carefully monitored, because we think that trying to

modify TSCA as a mechanism for governing the research has problems. We will certainly watch that with some interest. But at least the methodology that was used by the RAC in reviewing that, provides guidelines that could well be useful with regard to regulations by EPA, by FDA, and by USDA—all of which have legitimate interests in this area.

The second area I'd like to comment on has to do with the science and Government interactions. We think it's important that the regulatory agencies have the ability to carry out the long-range research in order to provide reliable data and analytical methods that can deal with environmental and occupation and health and safety risks. And I think that as these improve, it will improve the ability of Federal regulatory bodies to make their appropriate decisions.

At the same time that they're being asked to carry out increased functions, we note, with some concern, that the ability to carry out the relevant long-range research is being restricted in the funds available to these agencies. And that's particularly of concern to us as we look at the fiscal year 1987 budget for EPA. So we would hope that the Congress would look carefully at providing the funds that both EPA and FDA will require in order to make their decisions in the year ahead.

There are some models that can be carried out in a quasi-governmental way, and I'd like to call attention to the Health Effects Institute in Boston which has a good prototype, we think, for dealing with some of the EPA concerns. And if Dr. Goldberg, who has joined me, if there's a moment, I'd like to have him speak some time during this session with regard to that model.

The third one, and a very troublesome one, deals with the regulation on the research of animals. We are very appreciative of the legislation enacted last year by Congress, which we feel adequately deals with present enforcements and is largely sufficient. The new Animal Welfare Act amendments are a conscientious effort to improve the welfare of animals used in research while still recognizing the continuing need to conduct such research. We hope that in extending this, with the many concerns in the public, that the Congress will avoid legislation that will create further divergencies or be overly restrictive to the use of animals in not only our own discipline, in microbiology, but in many that deal with biological sciences.

It is clear that the use of animals is important for certain kinds of problems. We are very supportive of efforts to find alternative models, and to use these whenever possible. But there are instances in which it is difficult both to get the information available, or to verify that a model is useful unless animals are utilized.

So, in brief, we think that there are many areas in which both the scientific community as well as the Congress can address the trust that the public expects of us with regard to the conduct and the use of science.

Thank you.

[The prepared statement of Dr. Halvorson follows:]

STATEMENT BY HARLYN O. HALVORSON, PH.D., BRANDEIS UNIVERSITY

CHAIRMAN, PUBLIC AND SCIENTIFIC AFFAIRS BOARD, AMERICAN SOCIETY FOR MICROBIOLOGY

BEFORE THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

TASK FORCE ON SCIENCE POLICY

HEARING ON

"SCIENCE AND THE REGULATORY ENVIRONMENT"

MARCH 6, 1986

Mr. Chairman, Members of the Task Force on Science Policy, I want to express my appreciation for the opportunity to testify before the House Committee on Science and Technology on "Science and the Regulatory Environment." I would like to commend this Committee for bringing before it such a wide and balanced spectrum of opinions in reviewing the role the Federal Government plays in support of research. I appear before you today as a microbiologist, Director of the Rosenstiel Basic Medical Sciences Research Center at Brandeis University, Chairman of the Public and Scientific Affairs Board of the American Society for Microbiology (ASM), and as an individual who is actively participating with other scientists in responding to legislative and regulatory initiatives regarding policies that impact on scientific research. I am joined by Dr. Michael Goldberg, Executive Director of the American Society for Microbiology. The ASM has an active membership of over 34,000 individuals and is the largest, single life science society in the world. The members of ASM contribute to the applied fields of infectious disease, clinical microbiology, epidemiology, industrial fermentation process, ecological microbiology, agricultural and food microbiology as well as to the fundamental areas of immunology, genetics, molecular biology, virology, oncology, microbial physiology, environmental microbiology, mycology and host parasite interactions. The ASM has long had an interest in retaining the benefits of scientific research as well as in protecting the benefits of public health, safety and values.

This hearing to assess the effects of regulations for scientific research comes at a critical period for America's high technology which is in danger of falling behind that of Japan, Europe and the Soviet Union. As NSF Director Erich Bloch pointed out last week at the National Academy of Sciences (NAS) Government-University Industry Research Roundtable and in his article in Issues

in Science and Technology (Winter 1986), the U.S. is losing its position in economic competitiveness. His call for a new research strategy which will require difficult decisions and renewed self-discipline from scientists, the institutions engaged in conducting research and the federal government, is timely. This past week Senator John Kerry, in a letter to Science (28 February 1986), stated, "Today our national security strongly depends upon our ability to compete in international markets. That ability in turn depends upon a sound research base, able to fuel the technology and innovation needed to sustain our economic leadership. In order to maintain our position of leadership, we need strong support for science in the Congress and from the President."

Today, I intend to focus on three current topics which involve regulations and their impact on the health of American science.

1. Regulation of Biotechnology Research and Development

Most of the recent discoveries leading to biotechnology have been made in the U.S. The principal reasons responsible for this lead are the sound investment which Congress has made in funding of basic research in the U.S. and the responsible, sound, and flexible scientific oversight system exemplified by the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC).

The current interest in regulation of biotechnology is reminiscent of the circumstances surrounding the introduction of the original legislation to regulate recombinant DNA research. In this regard, it is important to remember the pivotal role that was played by RAC and its effects on such proposals. As background to this I would like to quote from my previous testimony almost ten years ago before the House Committee on Science and Technology: "The public furor over DNA research has now progressed to the point where some federal

legislation is inevitable. However, as further information becomes available the regulations will have to be modified. It is essential that any proposed legislation be flexible -- one cannot be too careful; advances in science are necessary for the health and well being of our country and such advances should not be discouraged by unreasonable restrictions."

As we know, legislation was not forthcoming, partially as a result of a close partnership between the academic community and the legislators prior to the development of legislation. Instead, the RAC played a singularly creative role in the regulation of recombinant DNA research. This Committee, in existence since 1975, has been composed of scientists, lawyers, ethicists, environmentalists, and members of the public at large. In its composition it has represented different positions concerning the perceived hazards of recombinant DNA research. The RAC's proposed actions are publicized in the Federal Register and its regular meetings are open to the public. The RAC has conducted business in an atmosphere of openness which has allowed the presentation of diverse points of view.

In our view, the RAC has managed a difficult assignment very well. It has acted responsibly and no harm to public health and well being has materialized from work done with recombinant DNA. On the other hand, the efforts of the RAC created an atmosphere of public trust, in which there is a belief in the expertise of the committee and in the mode of its deliberations. The RAC is evolving along with the sciences and is now considering the ethics of experiments in which human somatic cells will be modified.

To ensure continued U.S. preeminence in biotechnology, we believe it is essential to invest responsibility for scientific review and decision-making in

a Recombinant DNA Advisory (RAC)-like Committee and to assign regulatory authority for research and development leading to commercial products to appropriate federal agencies. The ASM is comfortable with the policy statements of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) concerning regulation of biotechnology research and development. The positions of these individual agencies and the ASM are consistent in regard to the need to make decisions concerning research and development of the products of biotechnology on a case-by-case basis, as is done for many other products under the jurisdiction of these agencies. The expressed willingness of each agency to work in collaboration with others within a single set of rules is indeed commendable.

Formal involvement of regulatory agencies such as the FDA and USDA, in addition to the NIH and NSF, will expedite research and development leading to applications of products of biotechnology in agriculture and medicine, and will help to safeguard environmental quality. But there is need to caution against regulatory requirements becoming unnecessarily burdensome. Moreover, flexible requirements must be established which are subject to modification and relaxation as circumstances warrant and experience dictates. This is an important lesson we have learned from the deliberation of the NIH RAC. The ASM believes that the Environmental Protection Agency (EPA) has made a critical mistake by considering regulation of biotechnology in terms of process rather than product. We are also concerned that the EPA has singled out products of biotechnology for more complex review and approval than products of other industrial processes and this seems both unfair and unnecessary and not in the public interest. This practice would be an obstacle to the development of biotechnology and could seriously compromise the position of the United States in international com-

petition. The EPA has not been given any specific authority in this area and the ASM is of the opinion that the EPA has not made a convincing case for its authority to regulate biotechnology under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). As long as the EPA continues to concern itself with process rather than product, its role and reason in regulation will remain clouded, and it will continue to be viewed by many as an obstacle to research and development in biotechnology.

In order to answer some of the scientific questions regarding release of genetically engineered microorganisms, at the request of then Representative Albert Gore, ASM hosted in June, 1985, a state-of-the-art symposium "Engineered Organisms in the Environment: Scientific Issues". After a productive dialogue on the scientific issues, Dr. Edward Adelberg summarized the views on those attending the conference on how research on the release of of genetically engineered organisms should be regulated. "Two recommendations were made and seemed to be well received: (i) We must avoid over-regulation, which could deprive society of the benefits of this new technology or could drive research and development into other countries where it might be done less well or less safely; (ii) We should emulate the process used in regulating recombinant DNA research, in which the orginal guidelines erred on the side of strictness but were deliberately designed to be relaxed as quickly as new information and considerations would permit."

We would like to add that regulation of biotechnology research and development can be counterproductive if it does not contain a time constraint within which Agencies respond and an appeal mechanism by which disagreements can be resolved. Research scientists have been discouraged by prolonged restraints imposed by federal agencies in the absence of demonstrable need.

2. Science and government interaction

We want to call attention to the importance of productive interaction between scientists and government agencies in order to rationalize federal regulation and to increase the reliability of data and of analytical methods on which estimates of environmental and occupational health and safety risks are based. The government should strengthen the scientific foundation underpinning the federal regulatory decision-making process. Scientists must be given a representative voice in contributing to debates on regulation of science and science policy. This is particularly important in the area of biotechnology.

Unfortunately, the environment for development of regulatations for science is adversely affected when regulatory agencies are being assigned new responsibilities at the same time that reductions in their budget deter entirely or eliminate the possibility of funding research to generate the necessary data base on which regulatory decisions are made. This is a Catch 22. It is unrealistic to expect that non-regulatory federal agencies (such as National Science Foundation (NSF) and NIH) will divert their limited resources to short-term mission-related goals. For example, EPA's flexibility in extramural funding is essentially eliminated in the FY 1987 budget. The ASM has consistently advocated increased funding for EPA's long-term exploratory research efforts. This is the time we should be increasing, not decreasing, the support for mission-related research in EPA, FDA, USDA, etc. Sound scientific information, not political decisions, should be guiding our regulatory policy.

This approach is particularly needed in developing a research agenda for evaluating the impact on the environment and the release of genetically engineered microorganisms. In the current budget climate, we would recommend that the "Health Effects Institute" of Boston is a good model to follow in developing a sound research base for regulatory decision making. It was jointly created by

EPA and the automobile companies to study the health effects of automobile emission. It takes no position on emission standards. The joint government/ industry funding and the public process by which research studies are selected, monitored, and evaluated, makes its studies credible. This mechanism has not only proven economical, it has lessened anxiety over regulations and established a partnership between the regulatory agencies and the scientific communities. We believe that it is timely to develop a similar institute in the biotechnology community - especially for the release of recombinant microorganisms to the environment. We invite the support of the Committee on Science and Technology in this venture.

3. Regulation of Research on Animals

My third example involves the effect of regulations on animal research. The legislation enacted by Congress last year should regulate adequately animal research and we believe that enforcement of present standards is sufficient. The new Animal Welfare Act Amendments are a conscientious effort to improve the welfare of animals used in research while still recognizing the continuing need to conduct such research. We are grateful to note that Congress avoided legislation which could have created divergent and overly restrictive standards and regulations which would cause confusion and disruption to research using animal models.

The use of animals in reseach is necessary if progress is going to be made in improving the quality and longevity of life in humans and in animals. The specific benefits to man and animals from the employment of animals as human surrogates in medical and basic research are numerous (testimony Rudy Wodzinski, ASM, NAS Feb. 11, 1986): studies on the establishment of virulence for new

infectious agents, particularly if the agent has a target organ; studies of the efficacy of new drugs or food additives, and the interaction of drugs, parti-ularly when the effects (accumulation, toxicity) are on specific organs; development of new surgical procedures for organ transplant or artificial organs; preparation of vaccine and antibodies - these are just a few examples of areas where animal studies cannot currently be replaced by alternative methods.

In studies where an alternative method may be available, the alternative has become possible only following correlation of results of the alternative method with animal studies. Also, these alternative systems generally do not show as close a correlation with the results in humans as do the animal studies that led to their development. Although many diseases have been ameliorated through research conducted with animals, with vast health and economic benefit to the public, several areas make the needed point, i.e., the progress in combating infectious diseases which would not have been possible without the use of research animals and an area in alternative methods on testing carcinogenicity. In a recent example, just two nights ago, CBS News showed premature infants suffering from hyaline membrane disease who survived thanks to a special breathing device. The research leading to development of the ventilator was done on baboons.

In summary, we should keep in mind the following needs:

1) the creation of a regulatory climate that will foster and not unnecessarily impede the exploitation of biotechnology;

2) the development of a regulatory science that will facilitate decision making. Joint ventures may be a useful adjunct to the efforts of regulatory agencies;

3) the continuing involvement of laboratory animals in research to benefit both animal and human health.

At this critical point in setting the agenda for research, we must all join in a partnership to ensure that the public health and well-being as well as our economic potential are maximized by our public policy decisions. Central to these efforts is the public's trust, to which we all owe a responsibility.

Mr. FUQUA. Dr. Goldberg, do you wish to comment?

Dr. GOLDBERG. I'd be pleased to make a comment about the Health Effects Institute if it would be helpful to the committee.

Mr. FUQUA. Maybe it would be appropriate at this time, if you want to come up to the table.

Mr. GOLDBERG. The reason why we wanted to bring the Health Effects Institute model to the attention of the committee is because it has the potential, we think, of serving as an example for a variety of other similar kinds of activities.

I think the important points to note about that model is that the Institute that was established is an absolutely autonomous and independent body. It's got a very distinguished board of governors which consist of Archibald Cox, Donald Kennedy, and William Baker, who is now chairman of Rockefeller University. Those three people select the staff, they select the review committees which are going to determine the nature of the research, and are responsible for the guidance and direction. And those are obviously individuals of absolute probity in that regard.

The second important point is that the Institute is jointly supported both by industry and by the Federal Government, so that, in effect, there's some degree of synergy with regard to the amount of resources that are available. It's certainly more money than either side can put in.

The third is that there is a very rigorous review process that takes place to assure that the research that is done is of absolutely the highest quality. And fourth and most important, I think perhaps, is that the research is what you might call generic applied research. It has a direction to it.

It is intended to provide information that will help regulatory decisionmakers. And it is not necessarily—I mean, it might be basic research, but is not undifferentiated basic research. And that's an important consideration.

What I think is lacking at this particular point in decisionmaking, for example, about the release of genetically-engineered microorganisms is a sufficiently reliable database on which determinations can be made. And that is one of the things, at least in the case of the Health Effects Institute which looks at the impact of automobile exhaust emissions on human health; it has a very specific targeted objective which couldn't necessarily be done by the Federal Government or by itself.

And so, for those four basic reasons, we thought we'd like to look into that Institute as a model for something that we could perhaps initiate, serve as the midwife to, maybe is a better way of describing it. That would be of help to both the industry and to the EPA and the USDA as they seek to find ways to assure to the public that there is an acceptable risk associated with genetically engineered microorganisms.

[A biographical sketch of Dr. Burger follows:]

DR. EDWARD J. BURGER, JR.

Dr. Edward J. Burger, Jr. is Director, Institute for Health Policy Analysis, Georgetown University Medical Center and is a member of the faculty, Georgetown University Medical School. He was born in Cleveland, Ohio, February 23, 1933. He holds a B.Sc. and M.D. degrees from McGill University and Masters and Doctor of

Science degrees from Harvard. Prior to coming to Washington in September 1969, Dr. Burger was a member of the faculty of the Harvard University School of Public Health and held a joint appointment in Science and Public Policy in the J.F. Kennedy School of Government. At Harvard, Dr. Burger was engaged over a period of approximately a decade in research and teaching in a department devoted to an understanding of the basic biological mechanisms of environmentally caused disease.

Beginning in September 1969, Dr. Burger served on the staff of the Science Adviser to the President in the former Office of Science and Technology. In this position, his responsibilities ranged broadly over a variety of subjects related to clinical medicine, the organization and financing of health care, biomedical research, family planning and population programs, food and nutrition, and the environment.

He was instrumental in helping to shape the President's health program in 1969 and 1970 which was announced by the President in his Health Message to the Congress in February 1971. In this setting, Dr. Burger was concerned for the Science Adviser with national health insurance, Federal programs and policies dealing with medical education and medical manpower, and biomedical research.

One of Dr. Burger's chief areas of concern was that of the health-related regulatory activities of the Federal government including those administered by the Environmental Protection Agency, the Food and Drug Administration, OSHA, and the Nuclear Regulatory Commission (the former AEC). Dr. Burger undertook for the Science Advisor, the President's Science Advisory Committee and the White House, a number of major reviews of policy issues—legal, administrative, economic and scientific—concerning government regulation and the protection of human health. The report, *Chemicals and Health*, undertaken by a Panel of the President's Science Advisory Committee at Dr. Burger's initiative, became the basis for a series of policy directions within the regulatory agencies.

While a member of the President's Science Adviser's staff, Dr. Burger helped develop a number of legislative initiatives which were eventually enacted into law. He collaborated in the drafting of the initial version of the Toxic Substances Control Act. He helped shape a number of other regulatory laws dealing with medical devices, pesticides, noise, air pollution and water pollution. As well, he assisted in the development of the National Cancer Act, health manpower legislation, the National Environmental Policy Act, various amendments to the Food, Drug and Cosmetic Act, and the legislation affecting the National Institutes of Health.

Between 1970 and 1976, Dr. Burger was responsible for helping to initiate and implement a number of international agreements and cooperative programs concerned with health and related issues. From 1973 to 1976, he was the leader of a U.S. delegation to the Organization for Economic Cooperation and Development for a project concerned with improvements in health care and social service functions through innovation. In December 1974, Dr. Burger was appointed Senior Scientific Adviser to the Economic Commission for Europe in the United Nations.

Dr. Burger has served on a number of advisory groups and panels. He was a member of the National Cancer Advisory Board and its Subcommittee on Chemical Carcinogenesis and of the National Advisory council of the National Heart, Lung and Blood Institute of the National Institutes of Health. He has been a member of numerous panels and committees of the National Academy of Sciences and the Institute of Medicine.

Between 1961 and 1964, Dr. Burger was on active duty in the Medical Corps, U.S. Navy. He completed his tour of active duty in 1964 with the rank of Lieutenant Commander.

Dr. Burger is a diplomate of the National Board of Medical Examiners and of the Medical Council of Canada. He is licensed to practice medicine in the States of Ohio, California, Massachusetts, Vermont, the District of Columbia, and in the Province of Newfoundland. He is Board Qualified, American Board of Preventive Medicine. He is a member of a number of professional societies and is listed in *Who's Who in Government, Who's Who in Health Care and in American Men and Women in Science*. He is a member of the American College of Preventive Medicine.

Dr. Burger is the author of nearly 100 professional articles as well as three book-length works, *Protecting the Nation's Health: The Problems of Regulation, Science at the White House: A Political Liability*, and *Health Risks: The Challenge of Informing the Public*.

STATEMENT OF DR. EDWARD J. BURGER, DIRECTOR, INSTITUTE FOR HEALTH POLICY ANALYSIS, GEORGETOWN UNIVERSITY MEDICAL CENTER, WASHINGTON, DC

Dr. BURGER. Mr. Chairman and members of the task force, I am pleased to have an opportunity to appear before the Science Policy Task Force to consider the question of the regulatory environment for science, and to contribute to a discussion of this subject as part of your inquiry into the components of science polity.

I am a physician and scientist. I hold a degree of doctor of medicine from McGill University and an additional doctoral degree in one of the basic medical sciences, physiology, from Harvard. For nearly a decade I was engaged in research and teaching at Harvard. I held joint appointments in the Harvard School of Public Health and in the John F. Kennedy School of Government. And during the 1970's, I served on the staff of the President's science advisor in the former Office of Science and Technology. I'm currently the director of the Institute for Health Policy Analysis at Georgetown.

The portion of your inquiry for which you have invited my testimony and discussion concerns the regulatory environment for science. I must say I do congratulate you for undertaking this extensive examination of science policy, and for the particular inquiry into control or regulation of science and the performance of research.

The title of this inquiry, "The Regulatory Environment for Scientific Research," covers a very broad list of endeavors. And indeed that breadth is reflected in the technical memorandum of the subject developed by the Office of Technology Assessment, which I think indeed serves as a useful background discussion. As discussed in that document, and in virtually all of the written materials on the regulation of science, the regulation covers a number of disparate concepts or activities, ranging all the way from guidance or targeting of the directions or priorities for research, as through the budgetary process; concerns for the tools or methods of research, which may at times be considered offensive to society; considerable concern for the technological output of science; occasional philosophical arguments against science itself or against the accretion of certain categories of knowledge; to concerns for fiscal accountability and considerations of health and safety risks occasioned by research. An inquiry into regulation also cuts across several of the issues that you have raised in the agenda for health policy review for this committee under the title of accountability.

For the purpose of my discussion, I will draw some more limited boundaries and attempt to focus on the relationship of Government and science—the relationship between science and politics. I will attempt, as some others have, to try to step back a bit and consider both historically and currently some of the pertinent national perspectives for what has become a traditional social contract between science and Government. Hence, I will try to address particularly the issues of the direction of research, the allocation of public funds for research, and public views and expectations. And I will try to illustrate my discussion with some examples in the biomedi-

cal sciences, where if I have any, perhaps that's where I have the strongest portfolio.

Much of the discussion of regulation of science, with which I am familiar, turns around concerns not for science, per se, but for the output or products of science. The contract between science and Government, under which Federal funds are made available to support scientists and research, is based on certain public expectations that social good will flow from in the public interest from science. Science was mobilized by the Government in its earliest period on behalf of exploration, mapping, surveying, construction of roads and canals, mining, and notably agriculture. The general proposition, an identity of purpose between Government and science—meaning products of science—has generally remained intact throughout the history of the Nation. Vannevar Bush's report to President Roosevelt based his proposals, in fact, for Government funding of science almost entirely on examples of applied science and technological benefit. The contract remains in place in part because of the success of the science community in arguing its case, using, quite properly, examples of expected, tangible benefits to health, to energy development, to national security, or to improvement in the Nation's economic position. But, importantly, the proposition remains true as science has, in fact, delivered on its promise over time.

While science has enjoyed a special relationship with the Government, there are aspects of this relationship which are, at the same time, exceedingly important and perhaps yet insufficiently understood, and from time to time in trouble. They require special attention both by scientists and by Government. The fact that science has been so successful in arguing for public funding has necessarily thrust it into the public arena and created, as a result, a demand for accountability. And this brings me to the issue of regulation. I believe that the scientific community has some obligations to provide assistance and explanation to the public policy process, and the political world must protect itself from putting its hands too deeply into the detailed direction of science. I fear that if these are not realized, there is the possibility that our pluralistic tendencies might lead us to compromise the very machinery upon which we depend so heavily for progress.

The period of public questioning of science and of the relationship between Government science began in the mid- to late-1960's. The rapid rate of increase in Federal support for research following the Second World War is a well-recognized bit of history. There followed, however, a period of new concerns, partly arising out of the very growth of science itself, and partly from a series of external factors. For the first time in its history, for example, the United States began to question some of the fundamental aspects of the ethic of growth—physical expansion, economic growth, and technological development. There emerged a national concern for externalities—undesirable side effects, often of technological developments. There was, too, a measurable concern in some quarters that technological development was generally demeaning to human dignity, an idea perhaps captured in many places, but, for example, in 1970, in Lewis Mumford's long piece in the *New Yorker* entitled "The Megamachine." Finally, there arose a widespread questioning of in-

stitutions of all sorts—public and private. And against all this, the special place of science and scientists suddenly became more vulnerable.

Let me illustrate these trends by pointing to the biomedical sciences. Here, as elsewhere, public support of science has been based on public expectations of beneficial outputs of science. The history of growth of Federal support for biomedical research is largely the history of the NIH and the National Institute of Mental Health. The appropriations for research grants for NIH amounted to $85,000 in 1945. The Palmer Subcommittee of the Vannevar Bush report recommended that the first appropriation for NIH not exceed $5 million, and perhaps rise no higher than to $20 million in later years. By 1955, in fact, the NIH budget was $155 million. By 1964 it was $2.74 billion, and in 1985 it was $4.82 billion. That budget increased at a compounded annual rate of 24 percent between 1957 and 1969.

Hence, the first decades following World War II witnessed a very marked increase in the national investment in biomedical research, and a supplementing or even supplanting of the private philanthropic sector by the Federal Government as the principal source of support. Beginning in the late 1960's, the rates of increase of Federal support began to slow down and there were actual declines in some sectors, such as construction and training.

Some from within the biomedical science community indicated their concern, in fact, very early on, over the long-term political implications of the rapid rise in the NIH budgets, and foresaw the possibility of relative stability. In a study on biomedical science for the White House in 1965, chaired by Dr. Dean Wooldridge, it was predicted that the NIH would shortly approach what he called—what that report called—maturity. That commission recommended an extra special effort to set priorities and to maintain the quality of its operations. One of their principal recommendations was the establishment of a new instrument, called a Policy and Planning Council for the biomedical sciences, to guide and assist in planning and policymaking. Interestingly, a similar recommendation had been made as early as 1958 by a prior advisory panel headed by Dr. Bayne-Jones. Unfortunately, and I believe unwisely, these recommendations were not acted upon. It is this very guidance that the political process needs.

The process of maturity of the support for biomedical research and of the relationship between the Federal Government and this sector of science has indeed come about. Financial support and continuity or predictability of support have become increasingly important issues. There has ensued a period of increasing competition among researchers. Most important, however, there has occurred increasingly frequent and increasingly direct political involvement in the directions for research. Questions of how to set priorities and allocate funds among categories or programs for biomedical research remain not well resolved. The augmentation of the National Cancer Program in the early 1970's was clearly an accommodation between the scientific and professional communities to express political desires. However, there have been numerous examples of specific public concern translated through a process of targeting into specific directions and detailed programs of research. Sickle

Cell Disease, environmental contributions to cancer, and AIDS research are illustrative. Presidential or congressional initiatives, as they are known, raise at least two hazards. Direct research attacks are often not immediately productive of expected goals—generally because of lack of sufficient basic knowledge or true opportunities for investigation. This, then, leads to a misallocation of funds and ultimate disappointment over raised public expectations.

Well, let me just summarize what I think are some lessons for public policy and for science from some of this history. No. 1, the Federal Government was persuaded in the 1940's to provide financial support for science, including basic scientific investigation, as an instrument in the national interest. This represented a commitment vastly different in scale than any before. It was also a qualitatively different commitment as it provided Government grant funds to independent, private universities, particularly, a pattern which both parties had actively shunned up to that point as improper and even unconstitutional.

No. 2, while the form of the dedication was new, the commitment rested upon an older tradition of Government support of applied science and engineering for national needs, and upon a faith that the technological products of research would be useful for national betterment. This implied relationship between investment in science and practical output is both part of the foundation for the commitment and also part of the present problem. That relationship needs to be frequently revisited by both scientists and Government, and needs to be expressed accurately and explicitly in order to assure the preservation of the important balance in the intertwining between science and public policy. Failure, or perceived failure, to preserve the relationship has probably contributed substantially to the uneasiness in recent years and has brought with it in its wake a series of other calls for, such as, accountability and regulation. That all is not well is recognized both by this inquiry as well as by other admissions by the scientific community.

No. 3, part of the problem arises from the many successes enjoyed by scientists in their seeking of public support for science over the years. That success in gaining public support has inevitably placed them and their endeavors into politics. Don Price noted this on several occasions, and wrote recently: "All the sciences together are the political victims of their own successes . . ."

No. 4, this raises additional responsibilities for both parties, scientists and Government, to help preserve the balance and the separation between them. To do otherwise, I think, threatens to put both at some peril.

No. 5, for scientists there is an important form of accountability to which they should contribute actively, frequently, and creatively. In the case of biomedical science, the Wooldridge report in 1965 called for an explicit effort within that sector to offer assistance to the political process in choosing among major priorities. The passive results of the peer review process are necessary, highly refined, but are not sufficient to this task.

No. 6, the policy process and the public need to understand much better the process of research, especially the time required between the initial investment and the practical outcomes. Flemming's observation of mold in the 1930's, identified as the breakthrough in

development of antibiotics, was, in fact, the end-point of over 50 years of careful work performed by hundreds of scientists. The present understanding of AIDS is the result of a massive amount of detailed work on viruses, cells biology, molecular biology, and immunology performed long before AIDS was recognized. Similarly, the success in conquering poliomyelitis came from a legacy of basic and applied investigation in areas which seemed at first quite unrelated to that disease.

No. 7, there is a need on the part of scientists for sensitivity to public concerns about the methods used by scientists, the tools of science, and about the potential end-uses of its products. In this regard, I believe that the process used to derive standards for recombinant DNA research was, in fact, a highly useful and successful model.

No. 8, the Government, for its part, should strongly resist the temptation to direct research in detail. The directions may not correspond to true scientific opportunities. Inappropriate direction or targeting will not permit science to deliver on its expectations and, worse, threatens to compromise the very machinery of science.

Finally, continuity of effort and predictability of support are of especial importance if the public is to realize with any efficiency its investments in science.

Mr. Chairman, I have a longer statement to submit for the record, if you would permit. And that's the end of my statement.

Thank you.

[The prepared statement of Dr. Burger follows:]

Written Submission
on
The Regulatory Environment for Science
Science Policy Task Force
Committee on Science and Technology
U.S. House of Representatives

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Washington, D.C.

March 6, 1986

The title of this inquiry, "The regulatory Environment for Scientific Research," represents a very broad list of issues. This breadth is reflected in the Technical Memorandum of the Office of Technology[1] which reflects a careful discussion of many of these issues. Thus, the term, regulation, has been associated with matters as diverse as:

1. Directions of the research effort - areas and subjects for scientific investigation. In some instances, the research effort is directed (typically via the budgetary process) to make it comport more closely to what are believed at the time to be features of the national interest;

2. Concerns for methods and tools of research which are seen by some as potentially offensive to society (e.g., use of prisoners as subjects for research, use of experimental animals);

3. Substantial concern for the technological output of science;

4. Occasional philosophical arguments against science, against the experimental method, and against the accretion of at least certain categories of knowledge;

5. Fiscal accountability - a matter made more important as science spends more public money and as government accounts more stringently for all public expenditures;

6. Concern for the health and safety of workers engaged in the process of research and concern over the broad implications for health and environment.

Any serious discussion of this matter needs to recognize this breadth, observe a working taxonomy and draw some boundaries around a more limited area of inquiry. I will focus my remarks on the issue of the relationship of government and science - the relationship between science and politics or the public policy machinery. I will attempt (as have some others) to step back a bit and consider some of the pertinent historical perspective for what has become a traditional social contract between science and government. Thus, I will try to address particularly the issues of direction of the national research effort, the allocation of public funds for research and the public's views and expectations. This is not to diminish the importance of the other issues under the term, regulation, although I believe that the relationship between

science and government is central to all of them. I will focus rather heavily on biomedical science as this is the area, perhaps, where I have the strongest portfolio for venturing any observations.

Traditional Contact Between Science and Government

The contract between science and government is based on certain public expectations that social good will flow from public investments in science. This issue, science for its social sake versus science for science' sake, is the one which distinguishes science from other endeavors, such as art. We have been encouraged since the earliest days of the Republic to look to pragmatic, tangible applications of science of benefit to the nation. The first examples concerned exploration and mapping of the terrain, coast and geodetic surveys, the construction of roads and canals, the exploration of extractable resources and, most prominently, the furtherance of agriculture. Science in these terms, was considered a servant which, in combination with democracy, would be a sure formula for human betterment or even for perfectability.[2]

The general proposition - the identity of purpose between government and science (meaning products of science) - has generally remained intact throughout the history of the nation. It remains, in part, because of historical events

(such as wars) where science and technology were explicitly mobilized and successfully applied for the prosecution of those conflicts. Vannevar Bush's report to President Roosevelt based his proposals for government spending for science almost entirely upon examples of applied science and technological benefit achieved during World War II and promised for the future.[3] It remains in part because of the success of the science community in arguing their cause, illustrated with examples of expected, tangible benefits to health, to energy development, to national security or to the U.S. economic position in a sea of international competition. But, importantly, the proposition remains true as science has, in fact, delivered. The systematic accounting of the place of biomedical science in medicine, performed a few years ago for the President's Biomedical Research Panel, is a good example [4]

Science has enjoyed a special relationship with government. However, there are aspects of this relationship which are at the same time, exceedingly important and yet insufficiently understood. The fact that science has been more successful in arguing for and achieving public funding has thrust it into the political arena. This brings me to the issue of regulation. I believe that the scientific community has some obligations to provide assistance and explanation to the public policy process and the political world must avoid putting its hands too deeply into the detailed direction of

science. I fear that if this is not realized, there is the possibility that our pluralistic tendencies may lead us to compromise the very machinery upon which we depend so heavily for progress.

Public Questioning of Science in the Present Era

The "present era," began awhile back. The zenith of governmental support for science occurred in the late 1960's. Similarly, major increases in support for the biomedical sciences occurred in the late 1950's through the mid 1960's. Federal appropriations to NIH and NIMH, largely for biomedical and mental health research, training and construction activities, increased at a compounded annual rate of 24% between 1957 and 1969. The same period (late 1950's and early 1960's) was noted for the national optimism toward the peaceful use of atomic energy, commercial gains from oceanography, technology for economic growth and trade with our European partners and for the exploration of speace.

There followed, however, a period of serious concern. Beginning in the late 1960's, the United States, for the first time in its history, began to question the ethic of growth - physical expansion, economic growth and technological

development. There emerged a national concern for externalities - undesirable side effects of economic activity - often activity arising from or worked by technological elements. At the same time, there developed a national questioning of institutions of all sorts - public and private.

Here, the special place of science and scientists suddenly became more vulnerable. Their particular call upon the federal budget, their special role as advisors to the corporate offices of the government and their perceived role in aiding an unpopular war, perhaps, all comprised to heighten the interest of at least certain sections of the public.

It should be noted that there has often been an element of concern for technology in society. There was a frequent fear that technological "improvements" would supplant human labor or reduce the dignity of human endeavors. Again, however, the feeling, perhaps, reached a new height in the late 1960's and early 1970's and was captured in pieces such as Lewis Mumford's, The Megamachine.[5]

Support of Biomedical Research. An Example

Here, as elsewhere, public support of science has been based on public expectations of beneficial output from science in the form of understanding of disease and opportunities

for medical intervention. The history of growth of federal support for biomedical research is largely a history of growth of the National Institutes of Health (including the National Institute of Mental Health). The National Institutes of Health had been established in 1930 as a successor to the Hygenic Laboratory. By 1937, Congress had authorized the National Cancer Institute and the first grants were made. (It is interesting to note that the political announcements of this event were accompanied by expectations for finding cures for cancer which were very similar to those accompanying the 1970 announced "war on cancer.")

The appropriations for research grants for NIH amounted to $85,000 in 1945. The Palmer Subcommittee of the Vannevar Bush report recommended that "... the amount which can be effectively spent in the first year (1945) should not exceed five million dollars. After a program is under way, perhaps twenty million dollars a year can be spent effectively."[3] By 1950, the level of federal support for medical research has reached $74 million, of which $25 million was attributed to the National Institutes of Health. By 1955, the NIH budget was $139 million. By 1974, it was $2.74 billion and in 1985 it was $4.82 billion. Hence, the first few decades following World War II witnessed a very marked increase in the national investment in biomedical research, and a supplementing and then a supplanting of the private philanthropic sector by the

federal government as the principal source of support. This period also represented an explicit shift toward the support of biomedical research in university laboratories and clinical settings rather than government facilities or freestanding research institutes.

In the late 1960's, the rates of increase of federal support for biomedical research began to show signs of reduction from their previous high levels. In some instances, there occurred actual declines. These declines were most notable in budgets for construction and research training. The NIH-NIMH support for the creation of new knowledge through research grants began a to decrease in 1967 due both to the decline in the purchasing power of the dollar and to the increase in the proportion absorbed by indirect or overhead costs of performing research.[6]

In 1965, there occurred a comprehensive review of the federal role in biomedical research in a report to the White House entitled, Biomedical Science and its Administration."[7] A major point offered in that review by the chairman, Dr. Dean Wooldridge, and his colleagues was the prediction that the NIH would shortly approach "maturity" and, therefore, an extra special effort would be needed to set its priorities and to maintain the "quality of its operations." In particular, the

Wooldridge Committee foresaw a period in which the former, continuously and rapidly rising Federal budget for this sector of research would be replaced by a time of relatively level funding. Or, as they expressed it, forthcoming was an "... era of relative stability in the fraction of the national effort going into health resources ...". Because of this leveling of of the Federal biomedical research budget, they predicted in turn that there would be, to an increasing extent, competing calls on a scarce resource and possibly, "... inappropriate government control". Because of what they perceived as the importance of these predictions, they offered as their principal recommendation the emplacing of a new instrument to guide and assist in planning and policy decision-making. This recommendation for an NIH Policy and Planning Council was never brought into being.

Others, in fact, had offered the same admonition years before. A previous review of this subject in 1958 led by Stanhope Bayne-Jones[8] had already recognized a remarkably rapid rate of growth of the expenditures for this sector of research and, most important, saw the development of dependencies or even Federal control within medical schools. Thus, the members of the Bayne-Jones panel of "consultants," while acknowledging this period of rapid expansion of biomedical research, feared a series of "... complex and serious problems ..." arising precisely because of these large sums of money. They foresaw a need for stability and

predictability and urged that a "... long-range policy for NIH be worked out promptly as an essential basis for the establishment of sound budgets for the organization." They also urged that "... heavy private funding of research (up to 50%) be maintained to provide for stability, adversity and to counter any negative effects of government funding."

The process of "maturing" of the support for biomedical research and of the relationship between the federal government and the sector of science has indeed come about. The rate of increase in financial support for research did change. Continuity and predictability of support became an increasingly important issue relative to the time periods necessary to perform in research. There has ensued a period of increasing competition among researchers. Most important, however, there occurred increasingly frequent and increasingly direct political involvement in the directions for research. How to set off priorities and allocate funds among categories or programs of biomedical research does not remain well resolved. The augmentation of the National Cancer Program in the early 1970's was clearly an accommodation between the scientific and professional communities to expressed political desires. However, there have been numerous examples of specific public concern translated through a process of "targeting" into specific directions and directed programs of research. Sickle Cell disease, environmental contributions to cancer and AIDS

research are illustrative. Presidential or Congressional "initiatives," as they are known, raise at least two hazards. One is their potential for diverting resources from other, fundamental research. The other hazard is that direct research attacks often are not immediately productive of expected goals. Allocation of funds for research toward social goals, however worthy, may not be well spent for lack of appropriate research opportunities and ideas. This leads to an eventual public disappointment.

The arrangement of the NIH activities into thirteen separate Institutes, most named by diseases or disease categories, was a skillful accommodation between science and the public policy process. Political manipulation of the research agenda - so-called micromanagement of research or targeting of research priorities - is fraught with perils and is guaranteed not to deliver expected outcomes in the form of new insight into disease and new therapies.

The creation of the Comprehensive Cancer Centers Program within the National Cancer Program in the early 1970's represented a brilliant political move. Indeed, it laid claim to a great deal of federal money. It put in place a substantial professional constituency which would be difficult to disappoint (if that were ever desired). However, the regionally distributed Centers, established to combine teaching,

research and service, have served to bring tangible and identifiable elements of the government's cancer program to the public in an exceptional fashion.

During the 1970's, there occurred increasing pressures to engage the NIH and its budget in behalf of the application of research and in the processes of assessment or evaluation of those applications. The origin of the President's Biomedical Research Panel in 1976 arose, in part, from public and Congressional inquiries favoring the acceleration of the process of moving the products of biomedical research into useful clinical practice. This urge to foster the translation "from bench to bed" led to expenditures by the NIH for controlled clinical trials which grew for a while at a rate much greater than did the NIH budget overall. Controlled clinical trials, often designed to determine the efficacy of a particular therapy, typically involve very large numbers of patients in multiple centers, require many years of follow-up, and obligate large amounts of money. (A single trial a few years ago to determine the effectiveness of a drug treatment for heart disease cost $42 million.) One of the ongoing highly useful, accommodations to this challenge was the Consensus Development Program of the NIH.

Conclusions. Some Lessons for Public Policy and for Science

1. The federal government was persuaded in the 1940's to provide financial support for science (including basic scientific investigation) as an instrument in the national interest. This represented a commitment vastly different in scale from any before. It was also a qualitatively different commitment as it provided government grant funds to independent, private universities - a pattern which both parties had actively shunned up to that point as improper or even unconstitutional.

2. While the form of the dedication was new, the commitment rested upon an older tradition of government support of applied science and engineering for national needs and upon a faith that the technological products of research would be useful for national betterment. This implied relationship between investment in science and practical output is both part of the foundation for the commitment and also part of the present problem. That relationship needs to be frequently revisited by both scientists and government and needs to be expressed accurately in order to ensure the preservation of the important balance in the intertwining between science and public policy. Failure (or perceived failure) to preserve the relationship has probably contributed substantially to

uneasiness in recent years and has brought with it in its wake a series of other calls for accountability and regulation. That all is not well is recognized both by this inquiry as well as by admissions by the scientific community.[9]

3. Part of the problem arises from the many successes enjoyed by scientists in their seeking public support over the years for science. That success in gaining public support has inevitably placed them and their endeavors into politics. Don Price noted this when he wrote recently:

> "All the sciences together are the political victims of their own success ..."

4. This raises additional responsibilities for both parties - scientists and government - to help preserve the balance and the cooperation between them. To do otherwise threatens to put both at peril.

5. For scientists, there is an important form of accountability to which they should contribute actively, frequently and creatively. In the case of biomedical science, the Wooldridge report in 1965 called for an explicit effort within that sector to offer assistance

to the political process in choosing among major priorities. The passive results of the peer review process are necessary, highly refined but not sufficient.

6. The policy process of the public need to understand much better the process of research - especially the time required between initial investment and practical outcomes. Flemming's observation of mold (identified as the breakthrough in development of antibiotics) was in fact the end point of over 50 years of careful work performed by hundreds of scientists. The present understanding of AIDS is the result of a massive amount of detailed work on viruses, cells, molecular biology and immunology performed long before AIDS was recognized. Similarly, the success in conquering poliomyelitis came from a legacy of basic and applied investigation in areas, which seemed at first, quite unrelated to that disease.

7. There is a need on the part of scientists for sensitivity to public concerns about the methods used by scientists, the tools of science and about the potential end uses of its products. In that regard, I believe that the process of derivation of standards for recombinant DNA research was a highly useful and successful model.

8. Government for its part, should strongly resist the temptation to direct research in detail. The directions may not correspond to true scientific opportunities. Inappropriate direction or targeting will not permit science to deliver on its expectations and, worse, threatens to compromise the very machinery of science. Continuity of effort and predictability of support are of special importance if the public is to realize with any efficiency its investment in science.

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Mr. FUQUA. Thank you. We will make the longer statement a part of the record. Dr. Burger, on the ending part of your statement before us. You find a lot of scientists that are engaged in basic research take the view that they're only engaged in research for understanding and truth about the nature of that project that they're in, and that the practical applications and knowledge of that are left up to the other people; the engineers and doctors and politicians, and so forth, to—who must take the responsibility for those applications. And if we accept all that, and whether or not we should I don't know, but how can we forecast and regulate research in those areas or those few areas where adverse consequences may arise, such as in recombinant DNA or such as using animals in research, or even in some of the drugs like DES and some of the others that have had adverse effects in the marketplace?

Dr. BURGER. Well, I—Mr. Chairman, I'm very respectful of that question. You must, I hope, infer from what I've suggested in my statement that I don't accept the initial premise. I do think that my colleagues in the scientific fraternity and their leaders, in particular, have some particular obligations which are not entirely fulfilled.

I think that the leadership of science has some obligations to assist the public's understanding and the public's thinking and the political process, including some attempts to try to anticipate matters of the sort that you've described. So, I think that's the important part of, I guess, my view on the subject.

Mr. FUQUA. Well, I guess what I'm really trying to get at is sometimes scientists, like politicians, can be trying—politicians trying to be scientists and scientists trying to be—let me not use the word politician, but public policymakers, tend to confuse their roles and maybe not understand the other role, other than the one that they're engaged in.

Certainly, politicians or public policymakers sometimes may be persuaded to infringe on the scientific freedoms that scientists should enjoy. And, certainly, we want to avoid that. On the other hand, scientists may be excellent scientists in the field, but their awareness level of some of the public concerns are not as high as it should be. How do you resolve that conflict without overregulating, or without doing damage to basic scientific research that should go on?

Dr. BURGER. It's been my——

Mr. FUQUA. And I'm not sure there's an easy answer to it either.

Dr. BURGER. It's been my experience that any group mobilizes itself typically when it feels the hot breath of public interest or public concern, sometimes expressed through its Congress breathing down its back; perhaps somewhat naively, but maybe not.

I am suggesting that the leadership of science, perhaps in collaboration with the leadership of the political world, in various ways that we haven't yet described, ought to do some extra homework, pull itself together, and attempt to provide some, if you like, national leadership from time to time, so that you don't feel quite

so much of that hot breath down your—down the back of your neck.

Now, that is a tall order, but I'm not sure that it's impossible. The British don't do badly in this regard. They have their parliamentary form of government, indeed makes things, their culture make things substantially different in many ways. On the other hand, they have an arrangement which provides some useful collaboration between the leadership of those two fraternities, government and science, including the Science Research Councils which, in a sense, provide a scientific basis for the British endeavors, some continuity of support, and an appropriate balance and even some isolation which protects both parties, I think that maybe we ought to give some consideration to in the longer run.

Mr. FUQUA. Dr. Halvorson, would you care to comment on that question?

Dr. HALVORSON. Well, there are two parts. One, I think that the scientific organizations, such as our own microbiology, have in recent years formed public affairs groups because of the concern that they need to communicate as well as interpret to their own members, as well as to decisionmaking bodies, like the House and the Senate. So that I think there has been a recognition of this need. And many of these same organizations have created rules of ethics which govern their own behavior. So, I would say in part that, although the partnership has not been as close as it probably should be between the conduct of science and the public policies resulting from it, that the movement is in the right direction.

I've also noticed, with a great deal of pleasure, the increased number of congressional fellows who are scientists that have come and helped to serve many of the Members of Congress and to bring to that body their expertise, and at least the searching out sources of knowledge and serving as a bridge. These are good directions.

We were concerned a few years ago when it appeared that the Science Advisor to the President would not be continued after—in the early years of the Ford administration. And we're pleased that that not only has come forward, but it has strengthened the advice the Congress has received from the very studies, such as the report that you have before you.

So, I think that we are doing a good job. I think we're doing a better job than England, and it's because they do not have the mechanisms for advising their people such as we have in the U.S. Congress.

With regard to specific hot issues that come up, we had an experience both in Cambridge and also in our own city of Waltham, when the city was concerned about the recombinant DNA issues. And after many nights of meetings with council members and members from the local scientific community, not only I think that they had a good understanding of what the problems were that were interpreted to them, but the scientists clearly understood what were the concerns of the local politicians. And an agreement, an arrangement, was worked out and resolutions have allowed the science to go forward in the community, and for the public to be reassured.

I think these can be addressed, but they're probably one-on-one issues.

Mr. FUQUA. Dr. Halvorson, are you familiar with any evidence of where the regulatory environment for basic and applied research in the United States has forced technology to be tested and developed outside of the United States?

Dr. HALVORSON. There has been a number of cases of vaccines being tested in massive levels outside of the United States: South America, Africa, and even in the USSR. I don't know for a fact whether these were a result of regulations, but they certainly were easier ways of accomplishing it.

There, certainly, was a danger of this happening in the early days when recombinant DNA came alone, that, in fact, companies would move to other countries. Fortunately, that didn't happen. So, I think that the danger of—the evidence for this in the past probably is minimal. Whether it will—whether regulations will drive companies elsewhere or science elsewhere, that remains to be seen. But I'm optimistic that the regulations that will ensue from the Congress will retain the pattern we've had in the past.

Mr. FUQUA. Let me ask both of you gentlemen another question that—should policymakers, in trying to set the agenda for science, be concerned only with the potential benefits that you get from proposed research, or should equal consideration be given to some of the risk proposed by that research? And is it possible to assess a risk in all cases? And if you're trying to do that, what are some of the guidelines that you should use in trying to make that determination?

Dr. HALVORSON. I think that's a very difficult question, and there have been efforts to do risk assessment analysis——

Mr. FUQUA. Well, we get some——

Dr. HALVORSON. And I think the scientific community does as well.

Mr. FUQUA. Certainly, certainly.

Dr. HALVORSON. With new information, of course, there's always the opportunity of benefit and risks associated with it. I think these go hand in hand. And one has to try to make the determination, what risk you are willing to accept for the anticipated benefits that will follow from it. So the environmental impact statement analysis has been a good one. Well, probably one should have an environmental impact statement for regulations as well.

Mr. FUQUA. That's been suggested. Or an economic impact statement.

Dr. HALVORSON. I would like to make one point in this regard, and that is that some years ago, when Dr. Steton was the director of the General Medical Sciences Insitute at NIH, he carried out an analysis of what was agreed to be success stories in biomedicine, and then track these back to find out where the information came from that allowed one to achieve success. And these, and all cases, were from unexpected directions, and largely from physics and chemistry came observations that eventually led to a success story in biomedicine. I think the pattern is a clear one that one does not know where the next new discovery is going to come from, but the track that it's likely to follow is probably fairly well predictable.

So that in the area of management of science, one has to recognize this and therefore not decrease the flow of information from the very basic sciences, such as—probably the difference between

Japan and the United States falls in this category. But at the same time one has to aid in the transmission of this information up the line. What may be applied to a physicist is basic research to a bioengineer, for example. And so, one does carry along both a basic science as well as an information transfer, and each stage of this needs to be encouraged. But I think unless one recognizes that it's unpredictable, and our future lies in supporting those sources of unpredictability, we may weaken our resolve and our strength in science.

Mr. FUQUA. Dr. Burger.

Dr. BURGER. Mr. Chairman, you asked whether members of the scientific community should be sensitive to the possible and unexpected side effects.

Mr. FUQUA. I meant the policy makers.

Dr. BURGER. Well, I guess maybe the answer—the broad answer is yes to both, in fact. How to do that——

Mr. FUQUA. We could include the scientists in there, too, but I was really speaking of in trying to develop science policy, should we try to look at whatever the end result might be, or should we include what might also be the risk associated with that?

Dr. BURGER. When speaking of basic investigation, I have to associate myself with Dr. Halvorson's comments. The end point of basic research is just generally unknown, in fact, in any terms that we would recognize around this table. And yet, it's a necessary ingredient for any progress down the line. So, yes, I think the scientific community and others should be sensitive to the extent they can to the possible implications and side effects of the endeavors. I'm not sure that's amenable to a standard treatment, and exactly how to do that I think is not clear. Again, I think the DNA research, recombinant DNA research record is a good one, and probably can be replicated in some instances.

Let me add one other point. And that is, the inquiry here leads us to be concerned particularly with the negative effects, or perhaps perceived effects, of science and research. I think that we may well be confronted with a time when we will wish to think more positively about how to mobilize science and technology maybe in a more structured fashion than we've done so far in the last several years for economic betterment. And that may preoccupy our attention as much as the question of regulation and breaks on the process, if you like.

Dr. HALVORSON. Could I add one more example to that?

Mr. FUQUA. Sure.

Dr. HALVORSON. One good example I think where the scientific community almost to a—has seen one type of experiment which we think is dangerous and probably should not be carried out. And that is extending the recombinant technology to the germ line in humans. Whereas there may be useful opportunities for dealing with some of our genetic diseases in somatic cells, we do not know enough about the genetics of the humans and know enough about the chromosome structure to make it safe to attempt to alter the germ line. I suspect this will be true for a long time to come, and it's a case where a responsible scientist would not carry out such experiments.

Mr. FUQUA. Mr. Lujan.

Mr. LUJAN. Thank you, Mr. Chairman. You know, what seems to make this whole thing very difficult of setting policy is that we suffer from a lack of interaction between—or amongst, I should say, the scientists, the engineers, the political people. One of my questions was, does that exist pretty much in like Japan, or places like that, that do seem to have very good research?

And being that that exists—I know that in our case, the only—the real interaction——

Dr. HALVORSON. We're about to lose our microphone, excuse me.

Mr. LUJAN. The interaction is very limited, at least, you know, from this side of the table to hearings like this, maybe meeting at some particular place, just happen to and had a little conversation, or on rare occasion on a particular subject to really sit down in one or another's office and discuss a particular project. So that interaction isn't very good in my opinion, anyway.

So, do you find, or do you know, the degree of interaction? You mentioned Great Britain. And then, second, you mentioned that Policy and Planning Council that has been recommended apparently in several studies. In what form would that take, where it would be based, and those sorts of things? I'd like to have a little discussion about that.

Dr. BURGER. Well, that particular recommendation was for an entity to be borne within the National Institutes of Health; an entity that was designed explicitly to mobilize some of the leadership of biomedical science to assist the political process, and it's thinking about how to allocate resources among broad categories. That process has not been done particularly well over the years. It's been done as a result of the buffeting of the political machinery and the constituencies in various parts of science; each arguing for its own area and sums of money.

I think frankly the reason it didn't come about because the various constituencies felt they would get less money if they did this systematically and explicitly. But I'm not sure that we can afford to keep on doing that. That's my point. I think one should revisit the spirit of that kind of a recommendation to mobilize, in systematic form, the leadership of the scientific community to assist in thinking about how to set some priorities among large categories of——

Mr. LUJAN. And what would be the composition of that council?

Dr. BURGER. Well, that one, I think, was proposed to be scientists. I'm not sure that it necessarily has to be all scientists, and that's a good point. I think that's a matter worthy of some discussion. It was the original—the original proposal was for an entity within the National Institutes of Health to assist its Director and the Department of Health and——

Mr. LUJAN. That still doesn't help us with that interaction that I see as——

Dr. BURGER. Well, except to the extent that it would provide advice to which you can point as legitimate counsel as to how to do that process, that then takes some of the weight off of your shoulders, I think. You can point to a legitimate body made up of recognized parts of the leadership as having done its homework well and thoughtfully. And I think that would be useful.

As far as true interaction is concerned, I think you're right. I think there is a place for that, and perhaps at a different level. If I may harken back to my earlier point, about the need for in the next several years for collaboration rather than regulation, I cannot—I would not propose that the Government try to target areas of economic activity with high technological components for singling out. Because I don't think we do that very efficiently. But I would propose that there is a place for some public-private collaboration to think about the areas of economic activity and their technological backgrounds, which will be necessary to allow us to compete in the international marketplace. And that certainly would allow some interaction, if you like.

Mr. LUJAN. Let me give you one example. For example, on the Animal Welfare Act amendments that we had, we get one side of it. You know, we get the "60 Minutes" and the "20/20's" and then the hundreds of letters into our offices, how inhumane, this sort of thing. We also recognize, just as individuals, that you have to use animals in research. But I don't really know why except that, you know—how can I say this very nicely so I don't get into a lot of trouble—that it's better to do research on animals than on human beings. Probably that's the way to express it. And that's just a general feeling that I have that that's the way it ought to go about.

But that decision and how that legislation was finally crafted was really very much just in the area up here, you know, what one of the Members would think and another one would think, and offer an amendment, and that sort of thing, without a lot of input, really, from—who was it, Pennsylvania State University that was doing the research? Those are the kind of interaction things that I'm talking about.

Yes, Dr. Halvorson.

Dr. HALVORSON. There were a number of conferences in the last few years trying to deal with the question of what were the concerns of animal welfare groups, and what were the concerns of the research scientists. And even in meetings which both of—groups of scientists representing both views have been brought together to try and discuss it.

And I know some of this information was shared with some of the committees in the Congress. Clearly it's been a very emotional issue, and it's one that one should try to sort out what really are the facts—the scientific facts—from what are the more ethical considerations.

I know out of this grew the probably more articulated view in the scientific community that the quality of the research extraordinarily depends upon the quality of the animals that are being used. And it's very important that one be very careful about not only the genetics and the care and the well-being of the animals, and at the same time deal with these in the appropriate numbers necessary to get the facts in which one could then make decisions.

So I think that we have gone a long way in the last several years by virtue of the debate that in fact has taken place.

Mr. LUJAN. Is this Health Effects Institute that you were talking about, does that have some kind of a guiding group of the regulators and the industrial users?

Dr. HALVORSON. Maybe Dr. Goldberg could speak to this.

Dr. GOLDBERG. I think, Congressman, that there are two ways in which that Institute tries to take into account both the concerns and the views of Government agencies and of industry. One is by placing reputable scientists from both communities on their review committees and on their committees that develop their research agendas.

I think the second, as I understand it, is that in the process of developing that research agenda in terms of deciding where they want to go, what kind of research they want to support, they sit down and they talk to a lot of people along the way. They may do it informally. I don't know that they necessarily hold a public hearing of any kind. But they do make an effort to sit down with the Environmental Protection Agency staff and say: "OK, what are your needs, what kind of science would you like to have done, so that when the information is available you can take it into account when you make your decision?"

They do the same, I think, with the automobile industry, and they also do the same, as I understand it, with a lot of the environmental public interest groups. So that although they are not directly represented, I think their views are very carefully listened to.

The only thing that they want to try to be careful about, as I have been told, is to assure that the ultimate decision as to how that research is done rests with that board of directors, those three individuals, so they can assure that they preserve a high degree of autonomy.

Mr. LUJAN. And are those three representative of the various interests? What I'm looking for——

Dr. GOLDBERG. Yes.

Mr. LUJAN [continuing]. Is some kind of an——

Dr. GOLDBERG. I think the answer to that, in a very general sense, is yes. I suppose one could argue, for example, that somebody like William Baker, who has been the president of Bell Labs, generally represents the industry view—not necessarily directly from the automobile industry because he doesn't have any experience, but is sensitive to the concerns of the industry.

I think Donald Kennedy, who was formally Commissioner of FDA and is now the president of Stanford, probably represents to some degree the public interest side since that is where, first as a working scientist and then as a public servant, he has devoted his energy. And I think Professor Cox probably has the most kind of catholic view of all in the sense that he represents, in effect, the most general public constituency and brings the law to it as well.

Clearly you can't—with a limited number of people you can't satisfy any specific constituency, but I think those three gentlemen, as well as any group, can take a large variety of interests into account.

Mr. LUJAN. What I was getting at is, you know, if we have the, I guess, semi-adversarial role, we need 100-percent clean air over here, well, this other fellow would say, "Well, that's fine except that it's going to cost $800 more per car to do that."

Dr. GOLDBERG. Sure.

Mr. LUJAN. You know, that sort of give and take, which seems to be a pretty good way to go about it.

Dr. GOLDBERG. Yes. I think if we, at least the society, were going to pursue this notion and investigate the possibility of establishing a similar institute, we would want to be very sensitive in terms of selecting or recommending for selection individuals who would serve as the board of directors, and assuring that all of those viewpoints would be adequately represented.

Mr. LUJAN. And you would see several institutes depending on the disciplines that we're talking about, or one big umbrella type of institute for the consequences of our actions?

Dr. GOLDBERG. Well, I think from our perspective right now we probably want—well, I can't say what we want to do. I can offer——

Mr. LUJAN. What you would like.

Dr. GOLDBERG [continuing]. A suggestion, which is that there is a specific need which is to look at the environmental consequences of the release of genetically engineered microorganisms. That's an area clearly where the American Society for Microbiology has had not only a lot of experience, but the individual members have participated on all sides of this debate.

And I would suspect that, given the Society's charter and its objectives, they probably want to limit themselves pretty much to looking at microorganisms, and not necessarily either plants or higher organisms. I think the general principles that might be established could be adaptable, and that might be one way of proceeding rather than setting up a whole parallel set at any one time. But we'd want to start in an area where, I think, we felt we could be credible to both yourselves and to any other organization that was concerned about this.

Mr. LUJAN. Thank you very much. Thank you, Mr. Chairman.

Mr. FUQUA. Mr. Packard.

Mr. PACKARD. Thank you, Mr. Chairman. I'm sorry that I was not able to hear all your testimony. I had two other meetings that I just couldn't leave. But in your judgment—and either one may answer—has regulation—and I'm speaking now in generic terms—been a cause of driving R&D in the scientific world overseas?

Dr. HALVORSON. I answered it earlier, so perhaps you may want to try.

Dr. BURGER. Well, I think one of the problems in answering that question is to separate regulation from other features of American economic life and Government activity, which also may be influential. The industrial activity and applied research and some basic research in the private sector on biomedical engineering, if you like, has been, as I understand it, in need of funds, in need of supporting funds, and has been attracted by the offer of funds from overseas companies from time-to-time, leading, in turn, to the export of the technology or the threat of it to, for example, Japan.

I'm not sure I can say that regulation in that case, for example, was the factor, and I'm not sure that it was, that has led to that particular trend. I think it's probably fair to estimate that regulation has added to the overhead of doing research business in general.

Mr. PACKARD. Do you have any idea of what kind of a percent of increase it might represent?

Dr. BURGER. No, I don't have one I can offer you, but I would be prepared to look at it.

Mr. PACKARD. Do you feel that regulation here in this country has been instrumental in driving scientists and researchers out of the field and into private sector, or into other fields?

Dr. BURGER. Well, anecdotally, I'm aware of complaints about the mechanics of accountability—if you like—accounting for time, for money, the accounting for the ethical aspects of the doing of science, which have been sufficiently frustrating to certainly make people complain about it and perhaps act as a factor which has reduced, for example, the number of physicians who have gone into research. It's a well-known observation that the number of M.D.'s versus Ph.D.'s who have gone into biomedical research has substantially dropped over the last decade.

But again I have to caution, I have to qualify my answer by saying that there have been other factors involved as well. One has to do with the increasing difficulty in simply gaining research funds. And another one has to do with the large debt that physicians take upon themselves when they go through medical school. So, I'm afraid it's a qualified answer to your question.

Mr. PACKARD. Well, I think it, of necessity, has to be a qualified answer. Obviously regulation is not a factor that can be isolated out to and quantified as to its effect upon either of these questions; whether they move out of the country, or whether they move out of the industry, or out of the field.

Has there ever been, to your knowledge, a definitive cost—benefit study done on the effects of regulation in the research area?

Dr. BURGER. Well, I believe some of the academic societies, and the American Association of Medical Colleges, have in fact examined this question to their satisfaction, I think, substantially. I don't have the results in front of me today, but I think the answer is yes, there have been some.

Mr. PACKARD. Dr. Halvorson.

Dr. HALVORSON. Well, I'll give you one small, specific example. In the last 3 or 4 years we've been involved in many discussions on A-21 with regard to time and effort reporting for accountability to the Federal Government. And in these, the analysis has been it added about 1 percent, for example, to the cost of indirect costs in doing research in universities.

I noticed with some interest the February 12 *Federal Register* on OMB's efforts to change A-21. Unfortunately, the time and effort report, removal of time and effort data, is not clear from their statement, and we're going to be looking at this in more detail. But certainly at that level there are numbers, and I think there are also some industrial figures available.

I recall Dr. Schneiderman, from Monsanto, addressing this question at our—one of our recent meetings with regard to the industry's component of that.

Mr. PACKARD. It would appear to me that there's a lot of hidden costs in regulation that you couldn't place it on the increased cost of a product or a product, actually. But behind that is perhaps a significant amount of cost to Government. And I'm wondering if there's ever been any quantification of that, or if there would be a need for a permanent commission of some sort that would oversee

and report on regulation generally, not just in the scientific world, but throughout the entire Government structure; some kind of a commission that would evaluate and follow up to see if any regulatory measures are producing the end result that they were designed to do? And are there side costs? Are there peripheral issues that have never been evaluated—what they're doing, the administrative costs, the enforcement, the loss of revenue, the loss of time, the paperwork? Do they create bankruptcies in the private sector? And how much does it cost the consumer in an end product? I'm wondering if there's ever been any thought given to having an overall agency or commission that has that sole responsibility to evaluate the costs and the benefit of regulation generally.?

Dr. HALVORSON. I would think this would be very desirable just as a sunset clause that would allow one to reexamine any one of the regulations to determine whether it has outlived its usefulness.

Mr. PACKARD. It appears to me that regulation, as we see it here and at all levels of government, is a power unto itself. It's enacted, and then no one really is accountable to report on it, or to evaluate it. That it's assumed that if the regulation is there, it's worthwhile. And that, of course, I think often leads to complacency in our regulatory process, and then we live with regulation that sometimes is counterproductive and perhaps expensive to the American taxpayer or the public consumer.

I really don't have anything further. It's just that I sense that—and I certainly appreciate the timeliness of this hearing. I think it's time we do evaluate what kind of problems we're creating in our entire regulatory process. We certainly are a body of regulation.

Mr. FUQUA. Thank you. I just have one further question. When we talk about the philosophies of regulation and control, how do we rationalize when we suspend those when the goal is probably exclusively, say, for national security use—say, a weapon system or a nerve gas or something of that type?

Dr. BURGER. I'll attempt to give an answer to that, Mr. Chairman, saying first of all that we certainly succeed in doing that, don't we, when we have a true war in place. The Second World War left no doubt about one answer to that question.

I also think that, properly, the country turns to, on behalf of other national priorities from time-to-time, and is quite willing to let its national shoulder be put against a matter when it feels it's substantially important. The space program was one of those, peaceful uses for atomic energy for a time was another, the war on cancer was another.

And I think it's fair to say that we are in a sense politically automatically willing in those times to strike a different balance than we are at other times. It does take some special handling in the intervening periods, however. And maybe that's what we're speaking about at the present time. There is a broad—for reasons I don't really understand fully, quite frankly—enormous interest in health in this country, an enormous interest in risks to health. And I'm afraid if we aren't more explicit about dealing with those concerns, they themselves take on a movement of their own and substantially influence your life in this body and the way the Government is forced to do its business.

I think they take some special handling on the part of both the responsible professionals and politicians, and we should think about that.

Mr. FUQUA. Dr. Halvorson.

Dr. HALVORSON. There's another component to this, and certainly we see this concern in the scientific community, and that is the accessibility of information. During peacetime, if we were to pay more attention to make certain that the scientific information that comes along is made available, so that it can be read by the scientists and by the lay public, many of these concerns can be diminished, because there are watchful people and concerned people that would follow the technology in both areas; both with the chemistry as well as biological warfare.

One is dealing with a spectrum that overlaps between fundamental research and also its application. So I will put my faith in the open communication of the results of the science.

Mr. FUQUA. Gentlemen, thank you very much for sharing your thoughts with us this morning. It's been very beneficial. Thank you very much.

[Whereupon, the Science Policy Task Force was adjourned at 9:37 a.m. to reconvene on Wednesday, March 12, 1986.]

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